GENE TECHNOLOGY, RISK, REGULATION AND COMMUNICATION

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REFERENCE GUIDE

KEYWORDS

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MeSH LIBRARY TERMS

Legislation [N03.706.615] ; Government Regulation [N03.706.358]; Social Control, Formal [I01.880.604] ; Government Regulation [I01.880.604.394] ; Social Control Policies [N03.706.825] ; Public Policy [N03.706.825.608] ; Risk [E05.318.740.600.800] ; Risk Assessment [E05.318.740.600.800.715] ; Uncertainty [E05.318.740.600.900] ; Environment and Public Health [G03] ; Ethical Analysis [K01.316.163] ; Consumer Participation [N03.540.245.360] ; Communication [F01.145.209] ; Interdisciplinary Communication [F01.145.209.381] ; Information Dissemination [F01.145.209.364]

ABSTRACT

This thesis examines the social, political and legal basis for the establishment of a national regime for the oversight of risks posed by **gene technology** in Australia. It provides an overview of the public debate about gene technology and considers how that debate served to motivate and shift the focus of regulatory reform which led to the ***Gene Technology Act* 2000 (Cth)** (GTA).

The debate about gene technology belies a much deeper social preoccupation with novel risk generally – something described by risk theorists as the '**risk society**'. This risk society has placed pressure on legislatures to manage the perceived risks posed by novel technologies or to use novel technologies to manage man-made or natural risks. Yet the traditionally prescriptive and cumbersome process of regulatory reform is ill-suited to the pace and transient nature of scientific innovation. Consequently, legislatures have developed a new legislative form, **risk governance**, designed to provide a more flexible scientifically based response to novel technologies. This form of legislation is exemplified by the GTA. Yet risk governance has proved to create problems of its own. Maintaining regulatory flexibility necessitates that rule making is virtually, if not officially, undertaken outside of the parliamentary process. Furthermore, because risk governance adopts a scientifically based assessment and management process (**risk analysis**) it must co-opt technical specialists (the subjects of regulation) into the decision making process. These factors have contributed to risk governance being perceived as anti-democratic in some quarters. Such perceptions are agitated by a growing distrust of technocrat's ability to serve the public interest in the risk society. Lack of trust was a major theme throughout the Australian gene technology debate.

The response to public distrust in technocratic oversight of novel technology has been the inception of **risk communication**, a process that encourages public involvement in risk analysis. Unfortunately, best practice risk communication has tended to be promulgated in policy but avoided in practice – something revealed with the commercialisation of gene technology. This has resulted in increased

pressure to put promise into practice by institutionalising participatory risk communication principles within risk governance. I have referred to this more democratic regulatory form as '**deliberative risk governance'**.

The GTA was enacted with the promise that it would involve the public in all aspects of regulating risks posed by gene technology. I consider how we arrived at such a system, if it matters and whether the promise of deliberative risk governance is real, efficacious and genuine within this act.

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ALRC. Australian Law Reform Commission.

Biosafety Protocol. *Cartagena Protocol on Biosafety* 1999.

CBD. Convention on Biodiversity.

CCI. Confidential Commercial Information.

Codex. Codex Alimentarius Commission.

Community Committee. Gene Technology Community Consultative Committee.

CSCG. Commonwealth State Consultative Group on Gene Technology.

Ethics Committee. Gene Technology Ethics Committee.

EU. European Union.

GMAC. Genetic Manipulation Advisory Committee.

GMO. See Genetically Modified Organism.

GTA. *Gene Technology Act 2000* (Cth).

GTCCC. Gene Technology Community Consultative Committee.

GTCCG. Gene Technology Community Consultative Group.

GTEC. Gene Technology Ethics Committee.

GTTAC. Gene Technology Technical Advisory Committee.

IOGTR. Interim Office of the Gene Technology Regulator.

IPPC. International Plant Protection Convention.

LMO. See Living Modified Organism.

NAS. United States National Academies of Sciences

NAS-NRC. United States National Academies of Sciences (NAS) and National Research Council

NHMRC. National Health and Medical Research Council.

NHP Guidelines. Guidelines For Assessing Human Health Risks From Environmental Hazards 2002.

NHP. Commonwealth and State Government National Health Partnership.

NLRD. Notifiable Low Risk Dealing.

OGTR Risk Framework. Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator.

OGTR. Office of the Gene Technology Regulator

OIE. Office International Des Epizooties (International Office of Epizootics)

R&D. Research and Development.

Red Book. The NAS-NRC Report, 'Risk Assessment in the Federal Government: Managing the Process' 1983.

SPS. Sanitary and Phytosanitary

TBT. Technical Barriers to Trade

Technical Committee. Gene Technology Technical Advisory Committee.

The Regulations. The *Gene Technology Regulations* 2001 (Cth).

The Regulator. The Gene Technology Regulator.

UNIDO. United Nations Industrial Development Organisation.

US. United States

WTO. World Trade Organisation

1

INTRODUCTION

As members of the modern society – particularly those of us in the developed world – we find ourselves at the forefront of a 'high technological frontier'.[1] This is a frontier in which boundaries are constantly being expanded and for which the future remains uncertain. This is a frontier undergoing a perpetual 'revolution'. Since the industrial revolution we have experienced scientific, technological and industrial advancement that has dramatically altered the life of every person on this planet, and indeed the very planet itself. No revolution before it has had such profound or widespread implications. It is, at once, a cultural revolution, a class revolution and a social revolution, fundamentally reforming living standards, public health and personal safety. It is a revolution that has dramatically altered the way we perceive our capabilities, limitations and future.

History has shown that revolutions rarely, if ever, achieve the utopia they promise. In the afterglow of social upheaval, when the euphoria of reform has died down, we often find ourselves questioning the implications of what we have done, or more aptly, what has been done on our behalves. The new system instituted to replace the old may create as many problems as it solves. Instead of freeing us from external control, it may simply have changed the agent controlling us. Ultimately we may feel no more empowered than before the revolution occurred.

[1] Giddens A, 'Risk & Responsibility' (1999) *Modern Law Review* **62**:3.

On the one hand, technology promises to, and indeed often does, liberate society from the constraints of social convention and the hazards of nature. On the other hand, many in society have come to perceive technology as both disempowering and responsible for the creation of more hazards than ever before, such as environmental damage, pollution, nuclear radiation and so on.

As society has had a chance to reflect upon the impacts of a technological revolution almost two centuries old, there has been something of a 'counter-revolution'. By this I mean that we no longer accept that technology will *prima facie* lead us to a better future. Rather, the uses to which technology is being put, the direction it takes and who controls it are increasingly being questioned. Hence this 'counter revolution' is one in which society struggles to regain control over both technology and its own fate.

Law has been the device to which we have conventionally turned to effect broad social reform and to control that which would otherwise control us. Yet law is a tool forged prior to the technological revolution. It was, as Justice Kirby notes, 'developed in the age of longbow and the horse-drawn cart', and may be ill-suited to the 'world of interplanetary flight, computications and bio-technology'.[2]

The law was designed to be applied in a measured, cautious and prudent form, through reasoned debate and formalised process. The technological revolution on the other hand, is constantly advancing and forever reinventing itself. It is not stable, but fluid and unconfined, presenting a 'frontier which absolutely no one completely understands and which generates a diversity of possible futures'.[3] Expecting the conventional legal system to effectively control technology can be somewhat like expecting the tortoise to capture the hare – not an absolutely impossible notion, but definitely a fantastic one. As such, Justice Kirby warned that:

> [t]he dazzling advances of scientists and technologists seem to have gone beyond the comprehension of ordinary people. The 'time cushion' which used to exist, within which lawmakers

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[2] Kirby M, *Reforming the Law*, Oxford University Press, Melbourne, 1983. pp 236-237.

[3] Giddens *op cit* 1.

> could prepare legal regulation to state society's standards, has virtually evaporated. Scientific and technological discoveries tumble out of the minds of these modern wizards. Slow-moving legal institutions find it hard to catch up … Unless we can adapt our lawmaking procedures from the current mediaeval forms, we must face the fact that increasingly our society will forfeit its control over social values long held important. Scientific experimentation and technological developments will carry us along where the scientist and the technologists take us. Our opportunity to evaluate the changes and assert human concerns will, in part at least be lost.[4]

More than two decades have passed since Justice Kirby's warning. Technology has certainly not paused to allow the law to catch up. Instead, it has advanced almost exponentially, infusing into every aspect of life, in ever-greater proportions, so that 'bio-technology' – at that stage little more than a vague notion than a real concept – is now at the forefront of the technological frontier.

This thesis explores these extent to which our law making procedures have adapted to the scientific revolution in the context of gene technology. The framework for this analysis falls under six broad themes which are discussed below. These themes are threaded through the thesis, which is divided into the four sections (groundwork, risk governance, deliberative risk governance, deliberative risk governance theory in practice).

1.1 GENE TECHNOLOGY

Gene technology ('bio-technology's' modern appellation) promises to broaden the scope of the technological revolution even farther, into even the basic structures of life itself. In chapter 2, I examine how the technology promises to benefit and impact on every aspect of human life, allowing an unprecedented level of control, not only over the food we eat and the environment around us, but to our very

[4] *ibid,* p 237.

physical makeup. I then turn to consider why the commercialisation of gene technology was initially met with the usual excitement and euphoria of scientific discovery, but was followed shortly after by social uncertainty, apprehension, fear of its 'hidden' risks and calls for legislative intervention [see chapter 3].

Regulators did not ignore the warnings of Justice Kirby and other legal commentators about the impending failure of the law to keep pace with technology. Whilst the process of legislating remains, to some, frustratingly slow – Australia took some ten years to put a regime in place – the form of legislation which is now being produced by that process has become more dynamic and responsive; able to capacitate the constant 'tumble' of scientific discoveries that fuel the technological revolution. This thesis examines that institutional response as part of the counter-revolution' of law making, with specific reference to gene technology.

1.2 THE GENE TECHNOLOGY ACT 2000

The *Gene Technology Act* 2000 (Cth) (GTA/the Act) was passed amid widespread community debate about the commercial introduction of gene technology in Australia [see chapter 3]. The Act is designed to 'allay' the 'substantial community concerns surrounding the introduction of [gene technology] into the market'. [5]

The GTA is intended to reflect a 'best practice' risk governance (risk governance refers to the overall process of regulating risk) system. It was designed to remain contemporary and capable of dealing with gene technology as it advances and develops [an overview of the Act is provided in chapter 4]. In order to do this, the modern risk governance paradigm (and the GTA) creates only a skeletal 'hard law' legislative framework [I explore these issues in chapters 6 and 10 at 6.2,10.1-10.3] and allows the regulatory agency to add, update or remove 'soft law' rules to or from the framework when necessary [see 4.5, 6.1, 10.4]. The hard law framework is intended to ensure that regulatory behaviour accords with

[5]Wooldridge M, *New Safety Measures For Genetically Modified Products*, Media Release (22/8/1999), MW80/99, Commonwealth Department of Health and Aged Care, Canberra, 1999.

parliamentary policy and to provide the regulatory agency with sufficient powers to regulate in the field. The soft law rules allow the regulatory agency to alter the form of regulatory intervention in line with technological advancement. Because of the technically complex nature of novel technologies, the risk governance paradigm allows regulatory agencies to utilise technical and scientific experts in the process of assessing and managing risk. Risk governance regimes such as the GTA are also premised on utilising and drawing upon international best practice rules and guidelines. This modern form of risk governance reflected in the GTA is meant to ensure that the law is malleable, flexible and science-based.

1.3 EVALUATING RISK GOVERNANCE (RISK & REGULATORY THEORY)

This thesis will look to the GTA, as a case example of whether the modern risk governance paradigm does 'adapt our lawmaking procedures from … mediaeval forms' and ensure that society *doesn't* 'forfeit its control over social values long held important.'[6] In examining the GTA however, I wish to go beyond merely examining the form of the law. As Laster points out:

> The highly formalised process of enacting legislation can conceal the political nature of law making. Lawyers, in particular, are usually unconcerned about the wider social context of law making. For many of them, the only question is procedural: has the law passed through the requisite formal states? … There are, however, much more significant questions usually not asked by positivist lawyers. Is it a good law? Should it have been enacted? Does it achieve its desired purpose?[7]

Laster is right, there is a very political basis to law making. As another author notes, it is 'citizens, scholars, lawyers, bureaucrats, and lobbyists' who actually prompt the inception of new legislation and often not legislators themselves. [8] Thus, in establishing what the 'desired purpose' of the GTA is, we must look to

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[6] Kirby, *op cit*, 2.

[7] Laster K, *Law as Culture*, Federation Press, Sydney, 1997, p 74

[8] Davies J, *Legislative Law and Process* 2nd ed, West Publishing, Minnesota, 1986, p 3.

what the community expected of it prior to its enaction. The Act was the product of a 'growing crescendo' of community concern, lobbying and activism [see 3.10.1, 0]. The basis for this concern was varied and I argue that there are a variety of stated and unstated reasons that the community deemed legislative intervention necessary [see 2.2-2.4, 13.2.3]. Hence, the GTA has several desired purposes depending on the perspective you take. Thus, a central question through this thesis will be whether the risk the GTA regime recognises and responds to the plurality of concerns in the community.

Looking at the stated reasons for legislating is very important, but I will also seek to go one step further to establish why the law has a role in technological risk at all. Some lawyers may see this as irrelevant or superfluous, accepting as axiomatic that it is the law's role to intervene. However, I contend that, in adapting the legal process to capacitate the technological revolution, the law itself has undergone major upheaval and major change (its own 'counter-revolution'). Just as the technological revolution creates new problems and new dilemmas, so too can we expect the legal revolution to have detrimental outcomes. In the rush for legal reform, we must realise that we could very well alter the law in a way that takes it far beyond its original scope, thereby undermining its original purpose. Understanding whether or not the new revolutionised legal form is 'good' requires a fixed reference point with which to contrast it to. If the law has no foundation then it is no different than the technology it has been called upon to regulate. Without a foundation the law will itself be caught in a 'tumble' of change and uncertainty, becoming part of the problem rather than a solution to it.

1.4 THE SOCIAL IMPLICATIONS OF PURE RISK GOVERNANCE (RISK SOCIETY, DE-INVOLVEMENT, ANTI-DEMOCRACY AND TRUST)

In chapter 5 I discuss the interface of society, technology, risk and law. The purpose of this discussion will be to examine, in greater detail, the dilemmas posed by novel technologies such as gene technology and the legislative response to such dilemmas. This discussion will detail how the legal response exemplified in the GTA has solved some aspects of the dilemma caused by novel technology

but created new ones. In particular it has created conundrums of its own because it takes the law somewhat beyond its original object.

It shall be my contention that law is a device, provided to the Parliament, by the people, to ensure that the people retain ultimate control over their own fate. Gene technology, as part of the technological revolution, is seen to have the potential to control society's fate. Hence, if novel technology is left unregulated, it will be technocrats (those who simultaneously promote and oversee technology) who decide society's fate, not law-makers. As such, unregulated technology will invariably be at odds with the objects of the law and the obligation society places upon Parliament. The greater and more powerful the control exerted by technology over society, the greater the need for Parliament to intervene. This is evidenced in the community *demand* for legislative intervention in gene technology as a response to the perception that, 'market driven multinational corporation[s]' should not be able to make the final decision about 'what is good or bad in a living organism'.[9]

I will argue that the intermeshing of technology and law within the risk governance process is both inevitable and necessary. Nevertheless, there are obvious problems in fusing the law with its subject matter, not least because some of the problems endemic to technology could be caught up in the regulatory system intended to control it. In particular, the potential for technology to undermine the people's right to decide their own fate, may creep into a system that relies so heavily on technology to make decisions. I refer to this situation as the 'control paradox' [see 6.4]. The control paradox arises because to adequately control novel technologies, risk governance has had to become more technically oriented and more reliant on external sources, such as international best practice and risk assessors. The result is less direct control by the community over the application of social standards to technology. This is firstly, because a great deal of decision-making is occurring at increasingly further distances from Parliament; and secondly because the process has simply become too technical for lay people (or even Parliament) to review and scrutinise. Thus, one of the main themes of

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[9]Murphy J, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29 August 2000, p19544.

the first half of this thesis is how the rise of risk governance has ironically resulted in what I describe as the 'de-involvement' of the public in the regulatory process.

1.5 RE-INVOLVING THE PUBLIC IN RISK GOVERNANCE (RISK COMMUNICATION)

The latter half of this thesis considers how the public can be moved back into a locus of control over the technology. In other words, if risk governance leads to the public being 'de-involved', what can be done to 're-involve' them so that the underlying object of the law is maintained?

Public distrust in the way that risk is overseen has been an ongoing theme throughout the commercialisation of gene technology and prior to it, in earlier technologies such as heavy industry and nuclear power. This has given rise to a variety of management approaches intended to assuage public concern about the risks associated with novel technology and the decisions being made in respect to those risks. Originally, such processes centred on communicating statistical risk data to the public in the hope that such information would confirm the technologies were safe and the decisions were correct. This came to be known as 'risk communication' and was largely unsuccessful in stemming public dissatisfaction.

The failure of early risk communication practice to engender trust in the risk governance process inspired a 'desperate search for salvation', [10] in which increasingly complex public relations methods were used to get decision makers' message across. However, it wasn't until those in charge stopped *telling people* what the problems posed by novel technologies were, and began to *ask them,* that any real progress was made. This more recent approach takes risk communication from being a unidirectional process to a multi-directional one, in which the risks posed by novel technologies are identified in deliberation with the public, rather than on their behalves. At least, this is what risk communication is *supposed* to be

[10] Slovic P 'Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield', (1997) *University of Chicago Legal Forum* **59:**61.

about. The participatory multi-directional form of risk communication often was cited as policy but neglected in practice [see 11.4-11.5]. Some of those charged with risk governance continued to make decisions in the absence of public input – albeit adopting a guise of multi-directional communication. Still others refused to adopt the new risk communication approach whatsoever and continued to tell the public that the decisions being made were right, and when the public refused to accept this, informed the public they were ignorant.

1.6 GUARANTEEING INVOLVEMENT (DELIBERATIVE RISK GOVERNANCE)

Nowhere was the often variable and sometimes dismissive approach to risk communication more apparent than in the introduction of gene technology into the marketplace [see 13.1-13.3]. Public concerns were treated with derision, objectors were called 'luddites' and reticent consumers were told that they would eat genetically modified food 'whether they liked it or not' [see 3.2.4]. Unsurprisingly, the public were less than receptive to this form of risk communication, and opposition to gene technology increased. In responding to these concerns, a growing emphasis has been placed on institutionalising multi-directional risk communication policy into 'hard law' legislative frameworks, so that what was promised is now guaranteed [see chapter 12].

This has resulted in a risk governance system that is generally more participatory and inclusive. It emphasises the need to do more than merely communicating risks, but rather render every aspect of regulating (*making, doing and enforcing law* [see 12.4]) more participatory. I refer to this evolving form of participatory law making as 'deliberative risk governance' and argue that it has been necessitated for two reasons. The first is to counterbalance the de-involvement of the public caused by flexible law making. The second is because conventional legal mechanisms such as accountability, transparency and representative government, that have conventionally been relied upon to guarantee democratic governance, are less than adequate in the face of the technological revolution. Whilst certainly these are not 'medieval' devices, they have already been left

behind by the rapid advance of technology, because they do not allow the public to adequately participate in the continued reformation of the law.

The GTA was enacted at the threshold of the move – both domestically and internationally – towards deliberative risk governance [see chapter 12]. I will examine if and how Parliament incorporated such processes into its legislative framework and what this means for the regulation of gene technology in Australia. In order to ask the 'significant questions usually not asked by positivist lawyers', as Laster encourages, I will consider not only the risk governance mechanisms within the GTA, but whether these processes are real, efficacious and genuine. I will also consider whether the GTA regime actually re-involves the public or whether it only *officially* reinvolves them. The attitude of risk managers to risk communication in the past indicates that this subtle question may, in fact, be a very important one.

PART I

GROUNDWORK

2

GENE TECHNOLOGY IN CONTEXT

The purpose of this chapter is to provide a background or primer to the *Gene Technology Act* 2000 (Cth) (GTA/the Act), as much of this thesis is dedicated to examining that Act in detail. It will assist addressing some of the central thematic questions in later chapters, namely: why was the enactment of this new legislative framework necessary; and what was it intended to achieve? In order to properly address these questions the following primer will first provide an overview of the subject matter of the Act, that is, gene technology. What the primer will also do is indicate the persuasiveness of the gene technology revolution. It will indicate the vast range of impacts on every aspect of living that this technology is hoped, and feared will provide.

A Limited Introduction. Whilst recognising that gene technology is a highly complex scientific subject matter, it must be emphasised that this is a legal paper. Therefore, I will not enter into an involved scientific discussion about the technology. Rather I have endeavoured to provide a succinct, lay overview of gene technology in the following section. I note however, that there are much more detailed primers on gene technology to which the reader may turn.[1] I would

[1]See for instance Biotechnology Australia's website <http://www.biotechnology.gov.au> (3/2/03), specifically under 'fact sheets'. See also the CSIRO Gene Technology Page <http://genetech.csiro.au/> (3/2/03). Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes,* Commonwealth of Australia (AGPS), Canberra, 2000: chptr 2.

also note that an ongoing debate about the advantages and disadvantages of gene technology continues to this day. It is not my intention to participate personally in this debate. Rather I wish to recognise that there are a broad spectrum of alleged advantages and disadvantages to the technology so that I may later examine how the plurality of public concerns are being dealt with by law.

2.1 GENE TECHNOLOGY PRIMER

DNA. All living things on the planet, known as organisms, are composed of cells, be they single cells or millions of cells. Within each cell is a set of chemical compounds known as Deoxyribonucleic acid (DNA). At its very basic, DNA is made up of three elements, sugar, phosphates, and a base (made up of a ring of nitrogen and carbon). There are four bases called adenine (A), guanine (G), thymine (T) and cytosine (C). The three elements are joined together in structures known as nucleotides, which in turn join into polymer (of many parts) strands. In most plants and animals, each piece of DNA is made up of two nucleotide strands – with the sugar forming the outer 'backbone' and the bases facing each other like the rungs of a ladder. The strands are twisted about each other in the form of a double-helix.

Genes. DNA is split into segments, referred to as genes. Genes contain enough chemical information to – 'at the right time and place'[2] – produce a specific protein that may change the cellular composition of the organism, its function, its characteristics or its appearance. Any alteration to the genes of an organism, be it through adding, removing or turning on or off various genes may change that organisms features.

Whilst DNA plays a dominant role in the characteristics of an organism, the interaction of that organism with the environment will also determine the appearance and functions of that organism. Hence, it will never be completely possible to predict the physical characteristics of an organism (its phenotype) from its DNA alone (its genotype).

[2]Senate Report, *ibid* 2.11.

Gene Technology. Gene technology involves the 'modification of genes or other genetic material' of an organism through artificial means.[3] It does not include sexual reproduction or conventional breeding processes such as the grafting of one plant to another.[4] Rather it involves direct manipulation of the genetic structure, through the use of highly specialised technology. This process is referred to as 'genetic engineering' or 'genetic modification'. Organisms that have had their genetic makeup altered by insertion, deletion, or the turning on or off of genes are referred to as 'genetically modified organisms'.[5]

Biotechnology. The term 'biotechnology' is often used interchangeably with gene technology. However, it is generally taken to refer to the mixing of organisms through any technology.[6] That is, it may include conventional methods such as sexual reproduction or grafting. The term often confuses the debate and I will avoid its use where possible from this point onwards.

2.2 THE BENEFITS OF GENE TECHNOLOGY

Gene technology is used for several purposes and has revolutionised many conventional disciplines and practices. The most basic use of the technology is for research, in particular researching the purpose of various parts of the genome. For instance, by 'knocking out' parts of the gene code and then growing the organism, scientists can investigate the function of removed gene and how it affected the physical characteristics of the adult organism. Gene technology may also be used to accelerate conventional breeding techniques. For instance the combination of traits from two types of tomato – one with resistance to frost, the other with a sweeter taste – may have taken several generations of cross breeding, trial and error to produce a tomato with the beneficial traits from each. Gene technology could potentially accelerate this process so that the final tomato species would be

[3] S 10, *Gene Technology Act* (Cth) 2000. [herein GTA]

[4] *ibid.*

[5] s.10, GTA.

[6] Office of the Gene Technology Regulator, *What Is Biotechnology? What Is Gene Technology?*, Fact Sheet, Office of the Gene Technology Regulator, Woden (ACT), 2002.

arrived at after only one generation. Finally, gene technology allows for the modification of organisms in a way that would have been impossible or near impossible with conventional breeding techniques. It allows traits from one organism to be expressed in other non-related organisms, – such as inserting fish genes into a tomatoes[7] – something which humans have never been able to achieve with earlier breeding techniques.

As a relatively novel technology, many of the applications of gene technology are either hypothetical or as of yet unproven, particularly in relation to the consumer benefits promised (as opposed to agricultural ones). Thus, the alleged benefits are open to debate. I include the below summary of the applications of gene technology to outline the *perceived benefits* which may derive from its use. This summary predominantly details the benefits evident in plant genetic modifications, as these have a longer and more established history than animal modifications.

2.2.1 RESISTANCE

Gene technology allows plants to be 'engineered' to have a natural resistance to pests and disease. Thus, proponents argue gene technology will naturally reduce the use of chemical pesticides that damage the environment. [8]

Plants can be engineered to be resistant to herbicides, thereby: increasing production efficiency; allowing for weed management (through specific targeting of weeds); and decreasing the amount of actual herbicides that need to be applied to crops.[9]

Gene technology can be used to effectively 'vaccinate' plants against common diseases. Post transcriptional gene silencing allows the insertion of an incomplete piece of viral DNA into plant genes which forces the plant to produce its latent

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[7] Senate Rept, *op cit* 1, para 2.31.

[8] Wolfenbarger L, ' The Ecological Risks And Benefits Of Genetically Engineered Plants;' (2000) *Science* **290**:2088.

[9] *ibid.*

defence mechanisms, making them virus resistant.[10] The plant is subsequently immune to the target virus.

The insertion of traits from rugged species, capable of surviving drought, salinity, or leeched soils into commercial crops is a suggested benefit of gene technology. Such environmental resistance in turn, argue proponents, will protect the environment by reducing fertiliser use. It will also reduce the labour and energy costs required to sustain large-scale commercial crops.

2.2.2 CROP IMPROVEMENTS

Gene technology promises to be able to increase yields by selecting traits which increase growth, crop size, hardiness and which produce more fruit or seed. This, it is claimed, will help farmers, increase the world's food supply and reduce the amount of land needed to grow crops. It could also lead to faster growing trees and higher quality grains. [11]

Genes that control the ripening of fruit and vegetables can be altered to permit longer storage.[12] This, it is hoped, will allow produce to keep longer, reducing wastage and spoilage.[13] Food could also be engineered to taste or look better. [14]

Bioremediation. By selecting beneficial traits, crops could be engineered to fix nitrogen in the soil, increasing soil nutrition and enhancing productivity. These bio-remedial crops could alleviate the stresses caused by monoculture farming and remedy damage already done. Genetically modified micro-organisms might also be used to break down toxic substances, such as oil or industrial waste.

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[10] Waterhouse P, "CSIRO: 'Hairpin RNA' Beats Plant Viruses; Scientists Have Found A Natural Genetic Mechanism That Can Change The Way Plants Protect Themselves Against Virus Attack", *M2 Presswire*, Jun 20/6/2001, p 1

[11] Anon., 'Tree-Mendous Debate', (2000) *Environment*, 4:**42:**5.

[12] Nemecek S 'Does The World Need GM Foods?' (2001) *Scientific American* 4:**284**:62.

[13] *ibid.*

[14] *ibid.*

2.2.3 HEALTH IMPROVEMENTS

Research in gene technology has also focused on providing health improvements to existing produce, by increasing nutritional value, vitamins, antioxidants, healthy fats and oils.[15] Other less healthy features of foods such as saturated fats could be decreased, as could allergens.[16] Trials have also been undertaken into placing pharmaceuticals within crops themselves. Gene technology can be used to produce vaccines, enzymes hormones and blood coagulation factors for use in human medicine.[17]

2.3 GENE TECHNOLOGY & HARM

Later in this thesis [see 5.1-5.3] I will argue that the perceived risks posed by gene technology extend beyond the mere physical. Thus, in the section below I will avoid the term *risk* and instead opt for the term *harm* which, at this stage, is more apt to describe the multifaceted concerns expressed about gene technology in popular and academic literature. These are a summary of the more popular arguments, but the list is not purported to be exhaustive.

It is neither my intention to paint a grim picture of a genetically modified world, nor idealise such a future. Furthermore, whilst I have placed these perceived harms within broad categories, I would emphasise that these are artificial distinctions as many of these concerns cross scientific, philosophical or ethical boundaries.

2.3.1 THE UNKNOWN HARM ARGUMENT

The most recurrent argument against gene technology relates to the 'unknown' consequences which might arise from its use. As may become evident below, concern about the unknown can also be seen to underpin many of the other

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[15]Morton O , 'Deep Impact' (2000) *New Scientist* 2224:**165**: 47

[16] *ibid.*

[17]Biotechnology Australia, *Background Information: Biotechnology in Medicine*, Information Sheet, Commonwealth of Australia (AGPS), Melbourne, 2000.

arguments raised by opponents. It is most often cited because of the sheer novelty of the technology[18] and a lack of comprehensive information about its long term consequences.[19] Such concerns were expressed in the Senate Community Affairs Committee (the Senate Committee [see 3.7]) in their investigation of the Gene Technology Bill:

> [t]here are concerns about the reliance on current scientific understanding to identify risks, particularly given past experience when it was discovered that scientific 'fact' turned out to be incorrect.[20]

Even with a map of a genome, the manifold functions of individual genes are often unknown or impossible to predict. Furthermore, genes express themselves in different ways depending on complex relationships with their environment. [21] Hence changes in the gene code may – some argue *will* – result in unpredictable outcomes.[22] For some, the unknown consequences of gene technology are a

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[18] In his submissions to the Senate Community Affairs References Committee virologist Professor Adrian Gibbs raised similar concerns about the use of viruses for genetic modification purposes. He cited a lack of 'scientific work being done at present on the safety to the environment of … those developments, and indicated this lack of knowledge 'worried' him. Gibbs A, 'Community Affairs References Committee: *Gene Technology Bill*: Discussion', *Community Affairs References Committee Hansard*, 25/8/00, p 429.

[19] Even in the U.S, a country renown for its promotion of GMOs, the peak US research body the National Research Council has recognised "Critics of biotechnology argue that the spread of beneficial traits could quickly lead to the spread of weeds; advocates of transgenic crops maintain that this risk is small or nonexistent. Empirical data with which to address the question are lacking. Many publications describe proposed methods for evaluating the effects of beneficial crop genes on the dynamics of wild, weedy populations … However, inadequate funding and restrictions on trial releases of transgenic pest-protected plants have hampered opportunities to carry out this important research before commercialisation … Until better data are available, it will be necessary to rely on general ecological and agricultural knowledge to predict the consequences of commercial scale, crop-to-wild gene flow from pest-protected plants." Committee on Genetically Modified Pest-Protected Plants, *Genetically Modified Pest Protected Plants, Science and Regulation*, Report to the National Research Council, National Academy Press, 2000, p 89.

[20]Senate Community Affairs References Committee *A Cautionary Tale: Fish Don't Lay Tomatoes*, Report On The *Gene Technology Bill* 2000, Commonwealth of Australia Canberra, 2000, par 2.56.

[21] Yoshida S, 'The Safety of Genetically Modified Soybeans: Evidence and Regulation', (2000) *Food Drug Law Journal* **55**:205.

[22]Many of the techniques used for the modification of genomes are 'hit and miss'[Ellahi B, 'Genetic Engineering for Food Production' (1994) *British Food Journal* 8:**96**:13.]. As such, critics argue that modification techniques may result in genetic 'instability', with unforseen consequences for a number of generations [Lappé M, Bailey B, *Against the Grain*, Common Courage Press, Maine, 1998, pp 4, 30]. Even if the new DNA is stable, it may cause changes in the way other traits in the organism express themselves. For

prima facie case against its immediate use[23], or at least applying the *precautionary principle* to it [see 10.1.3-10.1.4, Appendix 6].

2.3.2 UNNATURAL HARM ARGUMENTS

Gene technology allows us to cross hitherto impenetrable natural barriers. Some feel that these natural barriers *should not* be crossed because to do so is 'unnatural' or 'immoral'.[24] The absolute moral hazard view is also shared by those who believe gene technology undermines 'the order of things',[25] because 'nature is to be valued for what it is', an ethos reflected in international treatises such as the *Convention on Biological Diversity*.[26]

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example, the organisms may fail to produce vital nutrients or proteins. A commonly cited study claimed that Monsanto's Roundup Ready Soybeans were 12-14% lower in phytoestrogens, which are associated with protection against heart disease, osteoporosis and breast cancer. [see Tietel M, Wilson K, Nader R, Genetically Engineered Food : *Changing The Nature Of Nature*, Park Street Press, Rochester, 1999, p 48] However, all studies so far have been controversial, for instance see the debate over lectin gene modified potatoes, Enserink M, 'Preliminary Data Touch Off Genetic Food Fight', (1999) *Science* **283**: 1094-5; Enserink M, 'The Lancet Scolded Over Pusztai Paper', (1999) *Science* **286**: 656.

[23] The group Physicians and Scientists for Responsible Application of Science and Technology, an international consortium of physicians and scientists argue for the cessation of commercial gene technology as: "We find potential benefits of future [genetic engineering] irrelevant as long as it has not been established that this technology is safe. … there is much too little scientific knowledge today to be able to judge whether any safe and really valuable products will be possible to create at all. … The result is that unknown and potentially serious risks with public health … are now being taken for the sake of unproven benefits." Physicians and Scientists for Responsible Application of Science and Technology, 'Genetically engineered food Safety Problems', PSRAST website: <http://www.psrast.org/faq.htm> (8/12/02).

[24] Prince Charles, a vocal gene technology opponent, emphasised this point when he famously stated 'genetic modification takes mankind into realms that belong to God, and to God alone'[The Prince of Wales, 'Seeds of Disaster', *The Daily Telegraph, 8/6/1998, p A1* cited in, Prince of Wales Website <http://www.princeofwales.gov.uk/speeches/agriculture_08061998.html> (12/2/02)].

[25] Nuffield Council on Bioethics, *Genetically Modified Crops The Ethical And Social Issues*; Latimer & Trend Co Ltd, London, 1999, pp 96-97; also : "A belief that modern biotechnology is intrinsically wrong need not rest upon a religious basis. Agnostics and atheists would be unmoved by arguments about blasphemy, but might still share what seems to be a widely felt concern that biotechnology is in some sense 'unnatural' and therefore wrong", Straughan R, *Ethics, Morality And Animal Biotechnology*, Biotechnology and Biological Sciences Research Council (UK), Swindon, 2000, p 14.

[26] "The Convention on Biological Diversity (1992) not only recognizes the value that may be placed on particular organisms; it also acknowledges, as do countless cultures, that nature itself is to be valued for what it is." Food And Agriculture Organisation Of The United Nations. *Ethical Issues in Food & Agriculture*, FAO Information Division, Rome, 2001, p 4.

A less absolutist view of gene technology is to see only some cross species modifications as essentially 'harmful'. In particular trans-kingdom gene transfer and human-animal, or human-plant transfer tend to raise considerable opposition. People tend to consider this harmful for cultural,[27] safety[28], ethical[29], or religious reasons.[30]

Some oppose genetic engineering of animals and plants because, they argue, such research is merely undertaken to garner quantitative and qualitative data upon which to justify the practice on humans.[31] Thus, opponents see any research that would be, to them, unsafe, unethical or immoral in relation to humans, equally unwelcome in plants and animals.

For many, the reductionist nature of science coupled with the pressures of commercialisation will reduce life 'to a definition which only involves a

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[27] "Because science has uncovered the limitations of the concept of species at the genetic level, does not that automatically mean that the concept as a cultural category of meaning is no longer important?" Nicholas B, *The Ethical Issues of Genetic Modification, Background Paper to the New Zealand Royal Commission on Genetic Modification*, Wellington, 2000, p 14.

[28] Thibier M, 'Identified And Unidentified Challenges For Reproductive Biotechnologies Regarding Infectious Diseases In Animal And Public Health', (2001) *Theriogenology*, 9:**56**:1465-1481; Chan A *et al.* 'Reverse Transcription Of Inserted DNA In A Monkey Gives Us ANDi - Response from Chan *et al*' (2001) *Trends in Pharmacological Sciences*, 5:**22**:214-215; Anon., 'Roslin Clarifies Xeno Decision' (2000) *Animal Pharmacology* **451**:23.

[29] Barker J.H, Polcrack L, 'Respect For Persons, Informed Consent And The Assessment Of Infectious Disease Risks In Xenotransplantation', (2001) *Medicine, Health Care and Philosophy*, 1:**4**:53-70.

[30] Straughan R, *Ethics, Morality And Animal Biotechnology*, Biotechnology and Biological Sciences Research Council (UK), Swindon, 2000; Anon., 'Genetic Engineering Opposed For Religious Reasons', (2001) *AORN Journal* 3:**74**:406.

"Some will ask, 'If you can put new genes into a monkey today, how long will it be before you try to put some other genes into people' in an effort to improve them …" [Saltus R, 'Monkey Is Bioengineered To Allow Study Of Human Ills', *Boston Globe*, 12/1/2001, p A.1]. Embryo and stem cell research and cloning are also examples of this concern. "The cloning of Dolly in 1997 set off a wave of unease about the possibility of human cloning. Those who thought that if it worked, it might be a useful extension of ordinary human reproduction met with the charge that it would be an extension that simply went to far. Recent debates over GM crops have aroused exactly these sentiments." Ryan A, *et al*, *Genetically Modified Crops: Ethical & Social Issues*, Nuffield Council on Bioethics, London, 1999. para 1.33.

description of DNA'.[32] What it is to be a human, to be whole and to be alive is a strongly felt and intrinsic value, which we replicate on the world around us. Gene technology 'risks' undermining or destroying these values.[33]

The creation of animals that are only designed to contract disease – albeit for valuable research data – is a particularly sensitive issue.[34] Other experimental technologies, such as animal cloning, currently result in vast numbers of discarded embryos, miscarriages (suffering of the mother), infant mortality, and adult congenital disease. Opponents argue that such animal experimentation is an abhorrent and offensive waste of life.[35]

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[32][t]hose satisfied with purely utilitarian arguments … will simply want to weight up the benefits as expressed in terms of advantages to crops, efficiency of production or whatever it is and will be balanced against the short term dangers inherent in any new technology Edgar B, Chalmers D, *Transkindom Gene Transfer*, Report to the Gene Technology Ethics Committee (April 2002 Meeting), Office of the Gene Technology Regulator, Canberra, 2002, p 12.

[33]Straughan R, *Ethics, Morality And Animal Biotechnology*, Biotechnology and Biological Sciences Research Council (UK), Swindon, 2000, p 22. For instance, when chickens were bred to be featherless, so as to allow more 'streamlined' production, there was a great deal of public and media anger because 'we don't want animals resembling bleeding slabs ready to be shrink-wrapped' [Hitt J, 'The Year In Ideas: The Featherless Chicken', *New York Times Magazine*, 15/12/2002; p 90. see also Chiang M, 'You Can Do It' (2002) *Science World* **59**:21.]. Critics alleged that this breached the animals 'integrity' because life-forms should be allowed to preserve itself in its natural state [Bovenkerk B, *et al*. 'Brave New Birds. The Use of 'Animal Integrity' in Animal Ethics', (2002*) Hastings Centre Report* 1:**32**:16-22]. Whilst it is perhaps hard to remember a time when we did not treat chickens like commodities, this was crossing the line and seeing them as *only* commodities, not life deserving of respect.

[34] The most cited example is the Harvard Oncomouse, built to contract cancer for the purpose of research. Hence the one purpose of the mouse is to suffer, albeit for the good of others. However, critics argue that creating an animal, indeed a whole species of animal, with the intention an knowledge that it will suffer is immoral, unethical and cruel. King D, 'Ethics And The Oncomouse' (1995) *Genethics News* **8**:7; Abbott A, 'Harvard Squeaks Through Oncomouse Patent Appeal' (2001) *Nature* **414**:241; Salvi M 'Transforming Animal Species: The Case Of Oncomouse' (2001) *Science Engineering & Ethics*,1:**7**:15-28.

[35] Opponents of gene technology perceive it to subject large numbers of animals to testing, simply to examine the way that different genes express themselves, or how different traits will affect the animal in adulthood, without actually an actual purpose. To many this seems like 'pulling something apart' just to see how it works, then reconstructing it in a variety of different forms 'to see if it still works'. Moore C.J, Melpham T.B, 'Transgenesis And Animal Welfare', (1995) *Alternatives to Laboratory Animals*, **23**:380-397.

2.3.3 FOOD SAFETY ARGUMENTS

Altering the structure of food undermines some very basic sensibilities held by all humans.[36] Subsequently, there has been a prolonged public debate over whether consumers should be informed about the existence of GMOs in their food supply.[37] This is a highly politicised debate and will be dealt with extensively later [see 3.2, 3.4, 5.3, 13.2.2].

Outside of the basic 'right to know' argument against generic modification there are other grounds on which opponents challenge the use of genetic modification of affect organisms eventually intended for human consumption or use. In transferring target traits from one genome to another, proteins, which cause allergies,[38] may be also be transferred.[39] GMOs, or GMO product derivatives, to which a person had previously not been allergic, could potentially cause a reaction, due to the introduction of new proteins.[40]

Gene technologies can be used to introduce genes into host organisms which allow them to express biotoxins, intended for pest control.[41] Being constituent parts of the plant, biotoxins cannot be 'washed off'. Conversely GMOs have also been engineered to be resistant to herbicides. It has been suggested this may lead to increased spraying of herbicides by farmers (because the GMO crops are not

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[36]The right to food safety has been declared a fundamental human right. Articles 23 & 25 *Universal Declaration on Human Rights* (United Nations General Assembly) 1948.

[37] Some issues include, whether vegetarians and those with religious diets (kosher, halel etc) should be warned of the existence of genes or proteins from animals within their food, or whether indeed people who disagree at all with the use of GMOs because of ethical, health or safety reasons should be informed.

[38] Allergies are caused by hyperimmune responses to proteins in foods or the environment. These responses can vary from light agitation such as sneezing to debilitating and life-threatening, such as anaphylactic shock. Frick O.L, *Allergenicity: All Food Allergens are Proteins,* Policy Statement, Food and Drug Administration (US), 1992, p 22987.

[39] Early attempts to place a methionine-rich gene from brazil nuts into soybeans is an often cited as an example of this, as the gene also contains the allergenic properties of the Brazil nut [General Accounting Office (US), *Genetically Modified Foods*, GAO Report (GAO-02-566), Washington D.C, 2002.].

[40] What is even more problematic is that the allergenic potential for any one protein is hard to detect and measure. Frick O.L, *Allergenicity: All Food Allergens are Proteins,* Policy Statement, Food and Drug Administration (US), 1992.

[41] The Royal Society, *Genetically Modified Plants for Food Use,* Report Ref: 1/98, Royal Society, London, 1998, p 12.

affected by the application),[42] thereby increasing the amount of pesticides within the food supply.[43]

Finally, some studies have suggested that there is a minute chance that antibiotic resistance maker genes,[44] used in genetic modification, could transfer their resistance to bacteria in the human gut,[45] making them drug resistant.[46] The use of GMOs for other purposes (i.e. industrial or agrochemical) may also constitute a risk to human health and safety.[47]

2.3.4 ENVIRONMENTAL HARM ARGUMENTS

Critics of gene technology have argued that the release of GMOs into the open environment will cause harms to non-target species.[48] First generation GMOs, designed to provide agricultural benefits, particularly pest resistance, tend to be non-specific and thereby poisonous both to target and non-target species.[49]

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[42] Orson J, *et al*, *Gene Stacking In Herbicide Tolerant Oilseed Rape: Lessons From The North American Experience.* English Nature Research Reports No. 443, 2002, p 12; United States General Accounting Office, *Agricultural Pesticides: Management Improvements Needed To Further Promote Integrated Pest Management*, Report No, GAO-01-815, US Government Printing Service, 2001; Hassall & Associates Pty Ltd, *Genetically Modified Plants Farm and Resource Management Issues*, Report to the Rural Industries Research and Development Corporation, Publication No. 01/108, Barton (ACT), 2001, p 58.

[43] *ibid.* Note however that this is primarily a problem of management and not toxicology.

[44] The genetic devices used in the actual process of modification to trace transgenes. Antibiotic resistant genes are used routinely in gene splicing techniques to detect cells that have been successfully transformed. Savka M.A, 'How To Produce & Characterize Transgenic Plants', (2002) *The American Biology Teacher* 4:**64**:286.

[45] Coghlan A, 'Does It Matter If Genes Can Jump From GM Food To Bugs In Human Gut?' (2002) *New Scientist* **175**:6.

[46] Furthermore, merely consuming plants which produce the antibiotic resistant enzyme could in theory deactivate or diminish therapeutic drugs (such as kanamycin) in the human body. Huang F. C, *et al* 'Efficient Plastid Transformation In Tobacco Using The Apha-6 Gene And Kanamycin Selection' (2002) *Molecular Genetics and Genomics* 1:**268**:19-27.

[47] Such uses may include modified bacteria used to breakdown oils or toxic waste. Cribb J. 'Genetics Technology Anxiety Grips Nation' *The Australian* 23/5/1995 pg 8.

[48] Sands P, *In The Matter Of The Right To Impose Moratorium On Commercial Growing Of Genetically Modified Crops In The UK And In The Matter Of Council Directive,* Draft Legal Opinion, 90/220/EEC, Friends of the Earth, London. 1999, p 3.

[49] Commonly cited examples are Bt-Cotton trials in Thailand which caused a thirty percent mortality rate in bees in the test region [Ed., 'Cotton Used In Medicine Poses Threat: Genetically Altered Cotton May Not Be

Many GMOs are engineered for superior and advantageous traits.[50] Such organisms could dominate natural species if they either escape,[51] or breed with weeds.[52] In areas where this has occurred, farmers have returned to increasingly lethal combinations of conventional pesticides, placing a strain on local ecosystems.[53] Critics argue that GMOs threaten to destroy native landraces that provide genetic stability to domesticated plants[54] and render the ecosystem incapable of coping with disease or environmental changes.[55]

There is also a potential for insects or micro-organisms that feed on GMOs to become so called 'super-pests'.[56] Whilst insect resistance is a common problem in

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Safe' *Bangkok Post*, 17/11/1997, p1.] and the report that Bt-Maize was poisoning America's famous monarch butterfly caterpillars. [Losey J. E, Rayor, L. S, M. E, Carter, 'Transgenic Pollen Harms Monarch Larvae' (1999) *Nature* **399:**214] The report claimed that laboratory tests showed that monarch larvae were readily killed when they ingested milkweed leaves dusted with pollen from genetically engineered Bt corn. Subsequent debate has raged, with reports both supporting and attacking the original study from scientists, industry and environmentalists. See: Hellmich R, *et al*. 'Monarch Larvae Sensitivity To Bacillus Thuringiensis- Purified Proteins And Pollen' (2001) *Proceeds of the National. Academy of Science*, 21:**98**:11925-11930.

[50] such as virility, faster growth or flowering rates, resistance to pesticides or herbicides or higher durability in harsh soil and weather conditions

[51] The damage caused by introduced species in Australia, such as salvinia, lantana and cane toads is evidence of the risks that such species pose in an ecosystem where there are few or no natural predators.

[52] Seidler R.J, Watrud L.S 'Assessing risks to ecosystems and human health from genetically modified organisms'. In Calow P, (ed.), *Handbook Of Environmental Risk Assessment And Management*, Blackwell Science, Oxford, , pp. 110-146; Submission No. 54, p 3; (Organic Federation of Australia Inc): To Senate Community Affairs References Committee *A Cautionary Tale: Fish Dont Lay Tomatoes*, Report On The *Gene Technology Bill* 2000, Commonwealth of Australia Canberra, 2000. Submissions available at <http://www.aph.gov.au/senate/committee/clac_ctte/gene/submissions/sublist.htm> (24/2/03).

[53] *ibid* p 12. There is some evidence of cross pollination between weeds and GMOs in Canada, where farmers have resorted to controlling the plants with large doses of conventional pesticides.

[54]Quist D, Chapela I, 'Transgenic DNA Introgressed Into Traditional Maize Landraces In Oaxaca, Mexico' (2001) *Nature* **414**:541-543.

[55] Tietel M, Wilson K, Nader R, Genetically Engineered Food : *Changing The Nature Of Nature*, Park Street Press, Rochester, 1999, p 16.

[56] Topsy J, *Glusofisinate and Genetic Engineering*, The Pesticides Trust Report to Greenpeace International (Nov 1996), Greenpeace International, Brussels, 1996. The relatively short lifespan of insects and microorganisms meant that the evolution of such resistance can occur relatively quickly. McGaughey W, Whalon M, 'Managing Insect Resistance To Bacillus thuringiensis Toxins' (1992) *Science* **258**:1451–1455; Tabashnik B, 'Evolution Of Resistance To Bacillus thuringiensis' (1994) *Annual Review of Entomology* **39:** 47–79.

conventional crops, there is concern that exposure to toxins contained in plants could amplify such effects.[57] Critics posit that increasing doses of lethal toxins will be required to control such pests,[58] which may result in a diminution of species, or a disruption of biogeochemical cycles.[59]

2.3.5 ECONOMIC HARM ARGUMENTS

Organic farmers, whose status relies on being 'GMO-free' are particularly sensitive to cross breeding from GMOs.[60] However, conventional farmers may also be financially harmed because, if GMOs are detected in their crops they may lose valuable domestic or export markets.[61] In such a sense these GMOs could be considered weeds[62] or pests.[63]

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[57]Groot A, Dicke M, 'Insect-Resistant Transgenic Plants In A Multi-Trophic Context', (2002) *The Plant Journal* 4:**31**:387-406. A report by the Iowa State University into insecticide-producing plants stated; "Because more than 500 insects and mites already have acquired resistance to a number of insecticides, there is concern that similar resistance to Bt toxins could develop … Several major pests, including the tobacco budworm, colorado potato beetle, indianmeal moth, and diamondback moth, have demonstrated the ability to adapt to Bt in the laboratory. It has been reported that the diamondback moth evolved high levels of resistance in the field as a result of repeated use of Bt … As Bt use increases on more acres, some scientists predict that insect resistance to Bt will be a major problem. Considerable controversy exists about how Bt should be managed to prolong its usefulness." Webber D, *Insect Resistance Through Genetic Engineering*, Report of the Office of Biotechnology, Iowa State University, Report No. 553, Ames, 1998, p 13.

[58] US studies have also indicated that European Corn Borers can develop resistance to Bt, requiring 30-60 times the ordinary application of Bt to be killed. Ostlie K, Hutchinson W, *Bt Corn & European Corn Borer Long-Term Success Through Resistance Management*, University of Minnesota Publication BU-07055-GO, Minneapolis, 1997.

[59] Findley R, 'Legal and Economic Incentives for the Sustainable Use of Rainforests ' (1997) *Texas International Law Journal* **32**:20.

[60] The threat of controlled GMO products spreading through pollen and seed dispersal has been cited as a major rationale for banning open trials of GM crops. Leake C, 'Superweed Scare in Test Crop Blunder', *The Daily Telegraph* (UK), 18/8/1999, p 23. [60]Ed., 'Harrods Boss Sues Over GM Error', *BBC News* (U.K) 3/8/2000, <http://news.bbc.co.uk/1/hi/scotland/864210.stm> (12/12/02).

[61] The starlink situation in the United States showed how all farmers may be affected by the unwanted introduction of GMOs onto their property. Giese J, 'Sampling And Testing Corn For Cry9C Protein Residues' (2001) *Food Technology* 2:**55**: 60; Kaiser J, 'Panel Urges Further Study Of Biotech Corn' (2000) *Science* **290**:1867.

[62] At law a weed is merely a plant growing where it is not wanted. As Gyles J stated, "planting a seed of a plant which is regarded as a weed, but which has no other deleterious qualities, can be regarded as physical damage to property at all, it is physical damage of a peculiar kind, quite unlike some of the more striking

2.3.6 THE CONTROL ARGUMENT

One focus for critics against gene technology is control: how gene technology is controlled; by whom and how it might be used to control the very basic elements of life. Gene technology is a highly expensive, highly technical and highly specialised science. It requires large degrees of funding, support and infrastructure. This has resulted in commercial enterprise being, 'largely driven by a small number of major multinational companies' who have the resources to turn science into marketable commodities.[64] Moreover, these companies are consolidating, merging various aspects of technology including 'agribusiness and chemicals to health care and pharmaceuticals, to energy and computing' into 'what promises to be the largest industry in the world; the life sciences industry'.[65] Critics see farmers not as beneficiaries of gene technology but rather as unwitting 'victims' who will be overwhelmed by global markets to either perish, or acquiesce to the control of 'life science' conglomerates.[66]

Patenting. The patenting of genes, DNA sequences and methods for their isolation, has increased dramatically over the last decade.[67] Reach through claims, based on broad and obscure utility bases, allow control not only of the discovered gene, but all downstream uses, regardless of whether they were identified or considered at the time of gene discovery.[68] The fact that these claims relate to

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examples which can be given, such as the escape of fire." *Dovuro Pty Ltd v Wilkins* [2000] FCA 1902 (21 December 2000) at 185.

[63] Indeed Tasmania's moratorium on GMOs did so by placing them within the pest and weed legislation. [s. 8, *Plant Quarantine Act* 1997 (Tas)].

[64] Ryan A, *et al*, *Genetically Modified Crops: Ethical & Social Issues*, Nuffield Council on Bioethics, London, 1999. para 8.3.

[65]Enriquez J, Goldberg R.A, 'Transforming Life, Transforming Business: The Life-Science Revolution' (2000) *Harvard Business Review* 2:**78**:97.

[66] Mason, J. Singer P, *Animal Factories*. Crown Publishers, New York. 1980, p. 97

[67]Genes and other biological resources have been patentable since the landmark 1980 US Supreme Court decision in *Diamond v Chakrabarty*, 447 US 303 (1980) that granted a patent for an oil-dissolving microbe. For an overview of more recent developments see: Woessner W.D, 'Patenting Transgenic Animals — From The Harvard Mouse To "Hello Dolly"' (2000) *Futurics* **24**:32.

[68]This means that any subsequent use of the gene or derivatives must be approved by the owner and payed for by the user [*Amgen, Inc. v Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, United States

products, therapies or medicines has created apprehension, particularly in the third world, that life saving vaccines and drugs will be too expensive to use.[69] Further concerns including the ownership of life,[70] who controls it,[71] and how it is used,[72] are widespread.[73]

GURTs. Seed sterilisation technologies, known as genetic use restriction technologies (GURTs) are perhaps the most contentious agricultural gene technologies.[74] The earliest GURT was referred to by critics as, 'terminator

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District Court, D. Mass. No. 97-10814-WGY (2000)]. See also Tessensohn J, Yamamoto S, 'Enthusiasm Curbed: A Japanese View Of Biotechnology Reach-Through Claims', (2002) *Biotechnology Law Report*, 5:**21**:426-434; Kuckartz M, 'Commercial Exploitation Of Academic And Scientific Research Inventions - A New Duty For Patent Information Centres' (1999) *World Patent Information*, 1:**21**:27-29; Ryan A, *et al*, *Genetically Modified Crops: Ethical & Social Issues*, Nuffield Council on Bioethics, London, 1999. para.8.39.

[69] See for example Submissions No.38 (Mr J Sleeman), No.75 (Ms N George) No.35, p.15 (GE-Free Tasmania) to the Senate Committee :
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02); Lay Panel Report, *First Australian Consensus Conference on Gene Technology in the Food Chain*. Australian Parliamentary Library, Canberra, 1999. For academic debate on this issue see Williamson A.R, 'Gene Patents: Are They Socially Acceptable Monopolies, Essential For Drug Discovery?', (2001) *Drug Discovery Today*, 21:**6**:1092-1093, and replies by various authors in: (2002) *Drug Discovery Today*, 1:**7:**23-24; (2002) *Drug Discovery Today*, 2:**7**:102-104; (2002)*Drug Discovery Today* 6:**7**:346-347.

[70] Lebacqz K. 'Who '"Owns" Cells And Tissues?' (2001) *Health Care Analysis*, 3:**9**:353-368; Gosling P, 'Who Owns Nature?', (2000) *Accounting & Business* 10:**3**:14. Lipinski T.A, Britz J, 'Rethinking The Ownership Of Information In The 21st Century: Ethical Implications', (2000) *Ethics and Information Technology*, 1:**2**:49-71.

[71]Williams N, 'New Thinking On Gene Patents', (2002) *Current Biology*, **12**:577-578

[72]"[F]armers and consumers throughout this century have fought against the inclusion of food crops under the patent laws. Corporate control over plant varieties themselves has been regarded as contrary to the interests of the general population. … Patenting plant life will exacerbate … inequality. While centuries of innovation by indigenous farmers have created most of the food crops grown today, the tinkering by agribusiness entitles them to claim a plant as their own invention, and receive all profits from its use. This "biocolonialism" will continue the pattern of a few transnational corporations profiting at the expense of large numbers of indigenous farmers." Council for Responsible Genetics, *DNA Patents Create Monopolies on Living Organisms*, Report reproduced at :
<http://www.actionbioscience.org/genomic/crg.html> (12/12/02)

[73] Ryan A, *et al*, *Genetically Modified Crops: Ethical & Social Issues*, Nuffield Council on Bioethics, London, 1999. paras 3.35-3.67.

[74] The primary GURT was covered by three patents (US05723765, US05925808 and US05977441), under the head
Control of Plant Gene Expression' granted to the USDA-ARS and Delta and Pine Land Company. However there are more than 150 US patents listing barnase or site-specific recombination or both which achieve

technology' because it 'terminated' the reproductive processes of plants.[75] Subsequent developments allowed other traits to be 'turned off', including, but not limited to, reproductive processes.[76] The target trait can be 'turned on' by use of a chemical regulator.[77] The technologies have been heavily criticised [see 3.2.4], first because they give companies control of basic commodities such as food and secondly because they control farming practices.[78]

2.4 CONCLUSION

I would reiterate that it is not my intention to affirm or deny the veracity of any of the abovementioned arguments for or against gene technology. Such is the nature of a novel science like gene technology that many of the asserted advantages are yet to accrue and it is unclear if they are ever entirely realistic. So too must the asserted disadvantages or hazards of the technology be appraised critically because they too may not eventuate or may be overstated. This is however as far as I wish to delve into the debate about which advantages and which disadvantages are actually realistic, overstated or incorrect. As I have stated above

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similar sterilisation qualities. The oldest, on site-specific recombinase, going back to 1987 [US04673640 06/16/1987 Regulated protein production using site-specific recombination.]. However it is the Delta Pine and Land/USDA-ARS patents which are seen as most commercially viable and novel as they combine the terminator-gene system with the site-specific recombinase system, giving the company complete control over the hybrids as well as proprietary chemicals that control gene expression. Warwich H, *et al*, *Syngenta, Switching Off Farmers' Rights?,* GeneWatch UK, London, 2000.

[75] Rural Agricultural Foundation International *Terminator Two Years Later: RAFI Update on Terminator/Technology*, Rural Agricultural Foundation International, Report on Website : <http://www.etcgroup.org> (2/2/03), 2000.

[76] Other traits that have been targeted include taste, colour or disease resistance. See Warwich H, *et al*, *Syngenta, Switching Off Farmers' Rights?,* GeneWatch UK, London, 2000, p 12.

[77] *ibid,* p 7. It has been suggested that the chemical would most likely be included in fertilisers produced by the same company, thus guaranteeing not only seed sales, but tying in fertiliser sales too. Warwick H, 'Terminator Too', (2000) *The Ecologist* 3:**30**:50

[78] "The discourse on genetically modified plants/foods (GM crops) includes concerns about the socio-economic effects of introducing these products into commerce. What is the role biotechnology plays in the control of agricultural inputs to farming, in the autonomy of farmers, or in the rate of decline of the family farm?", Krimsky, S. 'Risk Assessment And Regulation Of Bioengineered Food Products', (2000) *International Journal of Biotechnology,* 1:**2**:232.

I would see that as part of a scientific, and political debate outside the remit of this thesis.

What is worth noting here for future reference is the broad spectrum of concerns about the technology (whether or not they are realistic or valid). The perceived harms of gene technology cross physical, environmental, economic, moral, ethical and legal boundaries. Similarly, there are vast arrays of possible benefits of the technology including: economic, agricultural, environmental, food and personal health benefits. We are then very much caught up in the 'tumble' of scientific revolution. We are presented with a 'frontier which absolutely no one completely understands and which generates a diversity of possible futures'.[79] With such potential, such uncertainty and such broad consequences how should such technologies be managed? Moreover who should manage them and who should take the decision to hold off on some or pursue others? As will be seen over the course of the next chapter, these were the questions faced by the community with the introduction of gene technology into Australia.

[79] Giddens *op cit* 1.

3

TOWARDS REGULATION

In the previous chapter I outlined some of the perceived benefits and harms of gene technology. This section discusses the social, political and legal debate following the introduction of the technology into the marketplace and which ultimately lead to the introduction of a comprehensive statutory regime for its oversight. I wish to provide an overview of what I see as the pertinent historical events that contributed to an environment in which regulation was deemed necessary. In particular I highlight the features of lack of public involvement, failure in risk communication and lack of process legitimacy.

This chapter takes the form of a historical time-line. I have opted for this largely sequential approach because it provides the reader with a clearer oversight of the path to regulation. This will help to show why a generally disinterested community became increasingly involved, active and interested in gene technology so that within five years there were a crescendo of calls for legislative reform that could not be ignored. This timeline also provides, what I believe is, a fascinating case study into what happens when novel technology is left unregulated and technocrats rather than Parliament are seen to be dictating society's fate. It doing so it supports arguments raised later in this thesis, namely that: there is a public fixation with technological risk [see 5.2]; risk perception is underpinned by a plurality of concerns [see 5.1]; the community expects government to take control of novel technologies and work with the community to resolve concerns about them[see 11.5] ; where the community is excluded they

will become politically active[see 13.2]; the resulting backlash can serve to motivate and shape the course of regulatory reform [see 13.3.3]. These themes will be expanded upon over the course of this thesis using this chapter as a reference guide.

Of course, to separate the history of the debate about gene technology and the various perspectives towards it is artificial. The debate did not arise out of entrenched attitudes to gene technology, nor did attitudes to gene technology form because of the debate. Rather, the public discourse forced more and more people to consider the impacts of gene technology, to form an opinion about it and express their concerns. This was an iterative process which created further discussion and the interchange of ideas and concerns.

3.1 PRE- GENE TECHNOLOGY ACT

Australia has, until very recently, had no comprehensive statutory body responsible for regulating gene technology. Instead, a number of non-statutory organisations have supervised GMO research and trials through voluntary agreements with research bodies and institutions.[1] In 1975, the *Australian Academy of Science on Recombinant DNA* was given responsibility for monitoring the use of recombinant DNA research.[2] This responsibility was passed to the *Recombinant DNA Monitoring Committee* in 1981 and then finally to the *Genetic Manipulation Advisory Committee* (GMAC) in 1987, which was provided a wider role in monitoring all genetic technologies.[3]

3.1.1 GENETIC MANIPULATION ADVISORY COMMITTEE (GMAC)

Originally under the Commonwealth Administrative Services Portfolio, GMAC was transferred to the Industry, Science and Tourism portfolio in 1996 and then

[1] Senate Rept, *op cit* 1, paras 1.5-1.10.

[2] *ibid.*

[3] *ibid.* .

finally to the Health and Aged Care portfolio in 1999.[4] I discuss the role of GMAC below as many of its features have been retained in the current regulatory framework.

GMAC's Role. GMAC was required to 'oversee' all genetic manipulation activities and to:

- keep up to date on risk information relating to genetic technology;
- inform Australian regulatory authorities, or other organisations using or researching gene technology of risks posed by gene technology;
- prepare, or assist the preparation of, codes, standards or guidelines for risk assessment and management of gene technology;
- facilitate harmonisation with international best practice for risk assessment and management of gene technology.[5]

The strongest feature of this scheme was GMAC's advisory role to State and Commonwealth statutory agencies that incidentally regulated GMOs. These areas included:

- genetically modified foods[6];
- therapeutic goods;[7]
- agricultural and veterinary chemicals;[8]
- industrial chemicals;[9] and

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[4] The below history was contained on the department of Health's website : <http://www.health.gov.au/tga/gene/gmac/backgrnd.htm> (last archived 24/3/00), and is archived at the *Centre for Law & Genetics* <http://lawgenecentre.org> [restricted access]. However the department of Health's website has been removed and replaced with an abridged history on the Office of the Gene Technology Regulator's website. <http://www.health.gov.au/ogtr/volsys/background.htm> (6/3/03).

[5] *ibid.*

[6] State and territory regulation regulate genetically modified foods, in compliance with the national food approval scheme established under the *Australia New Zealand Food Authority Act* 1991 (Cth).

[7] Regulation of therapeutic goods containing genetically modified material falls under the auspices of the Commonwealth Department of Health and Aged Care's Therapeutic Goods Administration.

[8] State and Territories regulate the post sale use of agricultural and veterinary chemicals containing genetically modified material in compliance with the national scheme established under the *Agricultural and Veterinary Chemicals Act* 1994 (Cth).

[9] State and Territory regulate the post sale use of industrial chemicals containing genetically modified material in compliance with a national notification scheme established under the *Industrial Chemicals (Notification and Assessment) Act* 1989 (Cth).

- quarantine.[10]

Outside this advisory role the GMAC scheme remained non-statutory and therefore voluntary, under which members of the gene technology industry undertook to comply with guidelines established for the use of GMOs in Australia.[11] These guidelines covered four areas:

- small scale contained work;
- large scale contained work;
- field trials and general release;
- activities with the potential for unintended release of genetically manipulated organisms.[12]

This distinction between different types of dealing has continued into the current GTA regime [see 4.5].

The major focus of these guidelines was on dealings involving the intentional or unintentional release of GMOs into the open environment. Those wishing to release a GMO, either for testing or for commercial use, were expected to seek GMAC's approval and comply with any guidelines it set down.[13] GMAC employed an independent committee of scientific experts to assess the information provided to them by the body responsible for the release of the GMO and recommend risk management schemes.

Dealings involving contained uses were primarily overseen 'in-house' by the institutions themselves or specialised committees who operated under GMAC guidelines. These committees – referred to as Institutional Biosafety Committees – monitored the work at local level.[14] They were assigned the role of ensuring

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[10]The Commonwealth (Australian Quarantine and Inspection Service & Australian Customs Service) controls of the import and export of goods containing genetically modified organisms under the *Quarantine Act 1908* (Cth), the *Imported Food Control Act* (Cth) 1992 and the *Customs Act* (Ch) *1901*

[11] *ibid.*

[12] *ibid.*

[13] *ibid.*

[14] Genetic Manipulation Advisory Committee, *Guidelines for the Deliberate Release of Genetically Manipulated Organisms (Field Trials and General Release),* Genetic Manipulation Advisory Committee (AGPS), Canberra, 1998.

that all stages of research and development were properly managed and assessed in accordance with GMAC guiding principles.[15]

3.1.2 STATUTORY GAPS

The GMAC scheme was a voluntary one and the Committee had no statutory enforcement powers, audit powers, or the ability to independently investigate breaches. The lack of statutory force in the scheme first came under serious critical governmental review in 1992 in a report by the *House of Representatives Standing Committee on Industry, Science and Technology.*[16] The Report recommended replacing the voluntary GMAC system with a regulatory system that particularly targeted GMOs released into the environment. The new regime, it recommended, should reflect Government policy, which was that:

- the new technologies have much to offer our society, not just in economic or commercial terms, but in improved environmental management and health care;
- like any other living organism, a GMO may survive, replicate and interact with other organisms in the environment and so it is prudent to assess the potential for significant risk to human or animal health, or to the environment; and
- there are concerns in the community about the technology and its possible misuse.[17]

In response to the Report, the federal and state governments established a Commonwealth-State Consultative Group on Genetic Manipulation in November 1992 to examine the most appropriate regulatory options. The body drafted proposed legislation which basically gave legal formality to the current GMAC regime. The GMAC would become a statutory body named the Gene Technology Authority with a core staff of 12 overseen by a part time board and assessment

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[15] *ibid.*

[16] House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* Report (February 1992), Commonwealth of Australia (AGPS), Canberra 1992.

[17] *ibid.*

committees. The body would be subject to direction from a Ministerial Council. The new Authority would develop risk assessment procedures for dealings with GMOs and ensure that those procedures were complied with. It was envisioned the scheme would be temporary having a sunset clause of seven years.

The Report and proposed legislation sparked an ongoing debate in both Houses of Parliament and at both state and federal levels of government. [18] The discussions, however, reached an impasse on the form and scope of a regulatory scheme. The states, Western Australia in particular, were less than happy about the complementary adoptive nature of the proposed legislation which would in practice allow a federal body to practically override state legislatures in an area they perceived to be within their jurisdiction. [19] At the Commonwealth level there was a degree of confusion and disagreement about which portfolio the regime would fall under. A lack of enthusiasm about the issue in the cabinet meant that little energy was put into resolving these issues. Subsequently, the passage of legislation necessary to create such a regime was frustrated, ceasing in 1995.[20]

3.2 THE COMMERCIALISATION OF GENE TECHNOLOGY (1995)

Another reason that talks about a regime failed was that, prior to 1995, interest in gene technology within the Australian community was minimal.[21] Because of the lack of public and media interest, few large scale studies had been undertaken to gauge public response to the technology. At that time only one Australian citizen group had any active involvement with gene technology issues, being the Australian Gene Ethics Network (GeneEthics), started in 1988, as a subset of the Australian Conservation Foundation. This lack of community interest would change drastically following the commercialisation of the technology in 1995.

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[18] Senate Rept, *op cit* 1, para 1.7.

[19] *Keal A,* 'History of Development of Gene Technology in Australia' (1998) *Plant Breeders Journal 11:**2**: 2.*

[20] *ibid.*

[21] See Polya R, *Genetically Modified Foods-Are We Worried Yet?*, Report of Science, Technology, Environment and Resources Group, Australian Parliamentary Library,1999 (e-version), <http://www.aph.gov.au/library/pubs/cib/1998-99/99cib12.htm> (12/03/02)

3.2.1 THE FLAVR SAVR TOMATO

The introduction of genetically modified foodstuffs into the international marketplace was perhaps the watershed for gene technology.[22] The first GM product was a tomato, entitled the FLAVR SAVR. It was engineered for 'delayed ripening', so as to improve transportability. The FLAVR SAVR was initially released in the US after receiving regulatory approval in that country in late 1994 and subsequently released in some other countries following that date. Although the product was never released in Australia its release in the US created international interest and it received some media and academic attention here.[23] The international attention resulted in several large scale surveys into public perspectives into genetic engineering being undertaken in various countries, including Australia.[24]

3.2.2 CDIST STUDY

In response to the release of the FLAVR SAVR tomato, the Commonwealth Department of Industry, Science and Technology (CDIST) commissioned the first comprehensive survey of Australian attitude towards gene technology in 1995.[25] CDIST researchers reported that the majority of Australians had 'heard' of gene technology. However a large proportion of people were not sure, or 'thought' that they had heard of it and 'for many others, a bit of reminding of what genetic engineering is about is useful to focus their thoughts'.[26] Hence, the survey team were required to 'educate' many of the participants prior to the study.

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[22]The actual approval of the FLAVR SAVR Tomato by the FDA was in late 1994 [see Meyer R, , 'Detection Of Genetically Engineered Plants By Polymerase Chain Reaction (PCR) Using The FLAVR SAVR Tomato As An Example' (1995) *Z Lebensm Unters Forsch* 6: **201**:583. Martineau B, 'Food Fight', (2001) *The Sciences* 2:**41:** 24-29].

[23] see Scalise D, Nugent D, 'International Intellectual Property Protections for Living Matter', (1995) *Case Western Reserve Journal of International Law*, **27**: 83

[24] see Kelley J, *Public Perceptions of Genetic Engineering: Australia,* Final Report to the Department of Industry, Science and Technology, May, 1995. (Revised August, 1997). Department of Industry, Science and Technology, Commonwealth of Australia, Canberra, 1997.

[25] Kelley J, *Public Perceptions of Genetic Engineering: Australia*, Final Report to the Department of Industry, Science and Technology, May, 1995. (Revised August, 1997). Department of Industry, Science and Technology, Commonwealth of Australia, Canberra, 1997.

[26] *ibid* at 5.2.

At the time the CDIST study was conducted, levels of interest in gene technology were moderate, with only ten percent of people surveyed reporting they were 'definitely interested' in the technology. This reflects the 'newness' of the technology, (at least from a lay perspective), and the lack of any commercial applications of gene technology within the Australian marketplace.

During this initial period, the potential benefits of the technology were perceived as outweighing potential risks, with fewer than ten percent of those surveyed believing that the risks outweighed the benefits.[27] Many were willing to eat genetically engineered food,[28] and most thought that first generation crop alteration was a good idea. However, when the survey team presented some of the potential risks of gene technology, those surveyed expressed a high level of concern [see Figure 1].

a. That medical genetic engineering accidentally create a new disease, something that might escape from the laboratory -- a worry

HUGE worry: terrible and very likely to happen	*32*
Very big worry	24
A big worry	18
A small worry	18
No worry at all	2

100% (mean=66)

b. That genetically engineered plants might get out of hand and spread on their own?

HUGE worry: terrible and very likely to happen	22
Very big worry	23
A big worry	26
A small worry	25
No worry at all	5

100% (mean=58)

c. That genetically engineered food plants might be a long run danger to human health, if people ate them for years spread on their own?

HUGE worry: terrible and very likely to happen	23
Very big worry	22
A big worry	26
A small worry	24
No worry at all	5

100% (mean=59)

FIGURE 1

For many of those in the 1995 study this may have been the first time they had considered genetic engineering in any tangible way. At that stage gene technology was a prospective science, which had little relationship to every day lives. As

[27] *ibid* at 10.2

[28] '[GE] cooking oil (60%), tomatoes (61%), and pork (56%) with most of the rest undecided rather than definitely unwilling.]'

such, survey participants expressed apparently conflicting perceptions of benefits and risks. Because the application of technology seemed a long way off, the risks were not perceived as actual, immediate or present. Therefore, the perceived future benefits of gene technology seemed to warrant its continued research and development.

The findings of the Australian survey were mirrored in several other countries. These studies found that genetic engineering was perceived as a warranted enterprise but also as being high risk.[29]

I will discuss the discordant high risk/high benefit perception of gene technology below [see 5.1-5.2]. However, it is worth placing the initial public reception of gene technology within the broader context of food safety, as that issue contributed to the high risk perception expressed by the public about novel food technologies.

3.2.3 A SHIFT IN PUBLIC PERCEPTION

During the late 1980s and 1990s several high profile food scares occurred internationally, the most serious of which were in Europe.[30] Of particular concern was the outbreak of Bovine Spongiform Encephalopathy (BSE) or 'mad cow' disease in the late 1990s.

Research following the BSE outbreak revealed that there may have been a suppression of 'inconvenient' scientific data, misrepresentations as to the dangers of certain foods and a silencing of subsequently 'legitimised' critics.[31] Related scares in Europe (including a cancer causing dioxin in poultry, pork and beef)

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[29] Hallman W, Metcalfe J, *Public Perceptions of Agricultural Biotechnology: A Survey of New Jersey Residents*, Rutgers, 1995; Anon., 'Public Perceptions of Agri-Biotechnology', (1995) *Genetic Engineering News* 13:**15**:1.

[30]McDonald F, 'Consumer Protection Policy In The European Union',(2000) *European Business Journal, London*1:**12**: 39-47.

[31] Manuelidis L, 'Penny Wise, Pound Foolish—A Retrospective', (2000) *Science*, 5500:**290**:2257 ; Jensen K, 'BSE in the UK: Why the Risk Communication Strategy Failed', *Journal of Agricultural and Environmental Ethics* 4:**17**:405 ; Anon., 'Food For Thought', *The Economist* (1999), 8127:**352**:20.

served to entrench the public's distrust of the industry and of government claims concerning the safety of novel foods.[32] Issues surrounding the BSE outbreaks have been dealt with extensively elsewhere.[33] I will therefore not revisit them in any great detail; suffice to explain that the global implications of that event – and the related food scares - have had a severe impact on public trust in the efficacy of food production and its oversight.

3.2.4 INTERNATIONAL COMMERCIALISATION AND INTERNATIONAL BACKLASH (1995 ONWARDS)

Multinational gene technology companies initially overlooked the public sensitivity to novel foods that had arisen as a result of the previous food safety scares. After spending such huge sums on research and development the gene technology industry were keen to introduce their products to the widest possible market and as quickly as possible. Many farmers and producers in the developed world, excited by the potential benefits of the technology [see 2.2] and encouraged by subsidies and discounting replaced conventional crops with GMOs.[34] The result was a dramatic upsurge in commercial GM crop production worldwide, with the total acreage of GMOs expanding some 15 times from to 27.8 million hectares from 1996 to 1998.[35] On the whole, this massive increase in GMOs gave little time for the public to consider or take on board the new

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[32] *ibid.*

[33] For instance see, Miller D, 'Risk, Science And Policy: Definitional Struggles, Information Management, The Media And BSE' (1999) *Social Science & Medicine*, 9:**49**:1239; Anon., 'Lambs To The Slaughter ' (2000) *The Economist,*. **357**:62 ; Manuelidis L, 'Penny Wise, Pound Foolish—A Retrospective', (2000) *Science*, 5500:**290**:2257 ; Healy B, 'vCJD: Broad U.S. Response Required' (2001) *Science* 5510:**291**:1859 ; Yam P, 'Mad Cow's Human Toll', (2001) *Scientific American*, 5:**284**:12 ; Martin E, 'Is The U.S. Doing Enough To Prevent Mad Cow Disease?' (2001) *Science*, 5522:**292**:1639 ; Yann P, 'Keeping The Mad Cows At Bay' (2002) *Scientific American*1:**287:**38-39.

[34] James C, Global Review of Commercialised Transgeneic Crops, cited in House Report, *op cit*, 1, para 1.4.

[35] i*bid.*

technology. Instead, it appeared that GM crops were *fait accompli* and the public were generally approached in a 'trust us its safe' manner.[36]

Monsanto, the leading gene technology company at the time, spearheaded the aggressive market push. The company was generally perceived as derisive to those who voiced concern and it refused (at least initially) to slow its progress and allow for public debate.[37] The comments of Monsanto CEO in a business journal were indicative of the industry's approach to public concerns. He suggested that 'experts' could take 'comfort of a sort from such obvious Luddism'[38] – that is, public concern and resistance to gene technology – because,

> [a]fter all, we're technical experts. We know we're right. The 'antis' obviously don't understand the science, and are just as obviously pushing a hidden agenda—probably to destroy capitalism. [39]

This dismissive attitude attracted a great deal of public criticism and anger. This anger spilled over from Monsanto to the industry it represented, that is, gene technology – particularly in agriculture and food. As a whole, the international gene technology industry compounded the problem. This occurred for two reasons. First, the industry generally tended to blame Monsanto for the public backlash against gene technology instead of dealing directly with public concerns as, '[i]ts Monsanto's problem ... [w]hy should we clean it up?'[40] Brooks argues that this attitude resulted in 'Monsanto's perspective' coming to be perceived as the 'industry perspective', which meant that consumers continued to be 'approached in a manner that aggravated them'.[41] Secondly, the stance of

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[36] Pollan M, 'Playing God In The Garden', *New York Times Magazine*, 25/10/1998, p 44 ; Newton J, 'Consumer Manipulation and the GM Food Debate When the Experts Say Trust Us, It is Time to Worry About the Future of Farming', *Sydney Morning Herald*, 10/4/2000, pA3.

[37]Hileman H, 'Prescription For A Global Biotechnology Dialogue' (1999) *Chemical & Engineering News*, 29:**77**:42.; Fairley P, 'Friend Or Foe?', (2000) *Chemical Week* 2:**162:**24-28.

[38] Shapiro R, 'The Welcome Tension of Technology The Need for Dialogue about Agricultural Biotechnology' (2000) *Center for the Study of American Business CEO Series*, **37**:2

[39] *ibid.*

[40]Brooks K, 'History, Change and Policy: Factors Leading to Current Opposition to Food Biotechnology', (2000) *Georgetown Public Policy Review* **5**:159

[41] *ibid.*

Monsanto encouraged other companies to push their products into international markets in an attempt to compete with that company.

On the whole, the industry considered opposition to gene technology to be unfounded and driven by illegitimate and unfounded concerns. It was generally expected that resistance could be overcome by a combination of education, advertising and public relations campaigns.[42] The public was informed that: they 'had nothing to worry about'; genetically engineered food was an 'inevitability' which they would 'have to accept eventually'; and that the safety issues associated with other novel food and farming practices had nothing to do with genetically modified food.[43] McGarity tells of biotechnology public relations specialist who informed critics that, 'people will have Roundup Ready Soya, whether they like it or not' and of another who told the head of a British supermarket chain that he was a 'backward European' who should 'just accept this is right for your customers'.[44] The Deutsche Bank commented:

> European consumers have recently been through the mad cow disease crisis, the French AIDS-tainted blood crisis, the Dutch pig plague crisis, the Belgian chicken dioxin crisis, the Belgian Coca-Cola crisis, etc. Therefore hearing that their fears are unfounded may not be the best way of proceeding.[45]

Both as a result of the recent food scares and the backlash to the public relations campaign adopted by the industry, gene technology was pushed onto the

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[42]For instance, British biotechnology companies undertook a concerted advertising campaign to promote the benefits of GMOs, including their beneficial impact on human health. In a country particularly sensitive to risk information following the 'mad cow' scare the publicity had the opposite affect of what was intended. Instead of creating support for their products the campaign actually caused an even farther reaching consumer dissent, as people who had not heard of biotechnology became aware that they were being sold mysterious and seemingly unethical products without their consent. see Anon., 'Food For Thought', *The Economist* (1999), 8127:**352**:19.

[43] Miller D, 'Risk, Science And Policy: Definitional Struggles, Information Management, The Media And BSE' (1999) *Social Science & Medicine*, 9:**49**:1239 ; Mann M, 'Genes, Greens and Global Trade Disputes', *Financial Times*(London), 26/7/2001, p 7 .

[35] McGarity T.O, 'Seeds Of Distrust: Federal Regulation Of Genetically Modified Foods' (2002) *University of Michigan Journal of Law Reform* **35**:473.

[45] Brown A, 'DuPont Ag Biotech: Thanks, But No Thanks?' Deutsche Banc Report, Deutsche Bank Securities, Frankfurt, 1999. p 5.

international agenda. An increasing number of consumers internationally (but particularly in Europe and parts of Asia) shied away from industrially farmed foodstuffs, turned to organically grown products and began questioning novel food technologies.[46] The response of US based multinational gene technology companies to this trend was the declaration of 'war against 'GMO propaganda', eliciting the help of the US government.[47]

The main weapon in the war against 'GMO propaganda' was the claim of 'substantial equivalence'. This policy is based on the premise that GM foodstuffs are 'substantially equivalent' to their conventional counterparts[48] and dictates that that GM products should be treated no differently to non-GM products.[49] According to the policy products derived from genetically modified organisms should not be labelled as being 'containing GMOs' and conventional products should not be labelled 'GMO free', because to do so would be to discriminate against identical products.[50] Labelling of GM products was something consumers in Europe and elsewhere wanted and the substantial equivalence doctrine was received by these groups as being 'anti-choice', 'anti-democratic' and proving the industry had something to hide.[51]

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[46]Dow Jones : October 5, 1999 'Japan Soybean Futures Down as GM Products Shunned', Wire Service: RTW (Reuters World Report) [Excerpts] 1/9/1999 Tokyo, Sept 1 (Reuters News Service (subscription) <http://www.reuters.com/>)- "Japan's largest maker of soybean protein food products, Fuji Oil Co Ltd, said on Wednesday the group will stop using genetically modified (GM) soybeans by next April due to consumer concern over the safety of bioengineered crops. Fuji Oil will start switching to non-GM soybeans in the October-March period, a company spokesman said. Until now Fuji Oil has not distinguished between GM and non-GM soybeans when placing orders. The Fuji Oil group uses 80,000-100,000 tonnes of soybeans annually, most of which is imported from the United States; see also Granitsas A, 'Mad About Cows', (2001) *Far Eastern Economic Review*; 8:**164**:21-23 ; Thayer A, 'Agbiotech' (2000) *Chemical & Engineering News, 40*:**78**:21-29. Graham R, 'Chirac Calls For End to Animal Waste in Feed, *Financial Times (UK),* 26/10/2000; p 8. Muil I, 'Genetic Revolution in the Century of Biology', *Australian Financial Review*, 19/11/1997, p 39.

[47] John Freivalds J, Natz D 'Overcoming Phood Phobia' (1999), *Communications World*, 6:**16:** 27.

[48] Spurgeon D, 'Call for tighter controls on transgenic foods', (2001) *Nature* 6822:**409**:749; Millstone M, Brunner E, Mayer S, *'Beyond Substantial Equivalence'*, (1999) *Nature*, **401:**525-26.

[49] Cantley M, Miyamura Y, 'GM Food, Regulation And Consumer Trust' (1999) *The OECD Observer* **216**:21-23

[50] Trewavas A, Leaver C. J., 'Conventional Crops are the Test Of GM Prejudice' (1999) *Nature*, **401**:640.

[51] Smith M, 'Brussels Mission To Take Fear Out Of The Food Chain: Commission Will Move Quickly To Plug Gaps In Safety Laws', *Financial Times*(UK), 27/10/1999, p 3; Milmo S, 'European Food Safety Faces Regulatory Reform', (2001) *Chemical Market Reporter*; 26:**259:** 12; Granitsas A, 'Mad About Cows',(2001) *Far Eastern Economic Review*; 8:**164**: 21-23.

Terminator Technology. The worldwide attention brought to bear on GM-food affected other aspects of the technology. Genetic use restriction technologies, or 'terminator' technologies [see 2.3], in particular, served as a conduit of public anger against multinational gene technology companies. From 1997 to 1999, Monsanto undertook to acquire the seed sterilisation technology from Delta & Pine Land, the company that invented it, creating anxiety among various public and private organisations worldwide about the social and economic impacts of its commercialisation.[52] Monsanto's initially refused to be swayed from attempting to further the advancement of this technology by such concerns.[53] The Rural Advancement Foundation International (RAFI) led a concerted eighteen month campaign against Monsanto and terminator technology, eliciting support from 'civil society organisations, farmers, scientist and governments all over the world'.[54] These groups placed a great deal of collective pressure on Monsanto, regulatory agencies and those purchasing the companies products. They raised public awareness and focused further public anger towards the company. The Executive Director of RAFI stated:

> [t]he public unanimously rejected Terminator because it's bad for farmers, food security and the environment ... Terminator has become synonymous with corporate greed, and it was met with intense opposition all over the world.[55]

The failure of Monsanto to adequately respond to the widespread concern and anger about the terminator technology ultimately lead to the demise of the technology and contributed to the downfall of the company itself. Faced with global pressure, as well as with potential intervention by antitrust regulators in the US, Monsanto was forced to withdraw from the contract to acquire the

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[52]Wrong M, 'Direct Action Protesters Attack Monsanto', *Financial Times (London)*, 9/11/1999, p.13 ; Slind-Flor V, 'Terminator Gene Reappears', (2000) *National Law Journal*, 26:**22**::6 ; Choi C, 'The Terminator's Back', (2002) *Scientific American*3:**287**:30.

[53]Townsend M, 'Meet The Company That Would Privatise Nature Itself', (1999) *Australasian Science*, **20**:42 ; Kluger J, 'The Suicide Seeds', *Time Magazine*, 1/2/1999, pp 44-46.

[54] Rural Agricultural Foundation *Suicide Seeds on the Fast Track: Terminator 2 Years Later*, Rural Agricultural Foundation International, <http://www.etcgroup.org/> (8/10/02).

[55] Vidal J, 'World Braced For Terminator 2', *The Guardian* (UK), 6/10/1999, <http://www.guardian.co.uk/international/story/0,3604,260202,00.html> (12/11/2002).

technology. The mistake cost Monsanto hundreds of millions of dollars in lost research and development and in merger-termination fees.[56] By 2000, Monsanto had been taken over by Pharmacia and Upjohn, a pharmaceutical company. After an internal reform and restructuring, the company admitted it had, 'missed the fact that this technology raises major issues for people -issues of ethics, of choice, of trust, even of democracy'.[57]

3.2.5 THE INFLUENCE OF THE INTERNATIONAL DEBATE ON AUSTRALIA

The internationalisation of the gene technology debate influenced Australian attitudes and changed the socio-political landscape here. As the Australian Wool Board noted to the Senate Committee investigating gene technology:

> [t]hese days, it is a global world out there. If our customers overseas see that there are serious breaches here in Australia, for whatever issue, whether it is a GM issue or a food safety issue, they know about it, and they start to raise questions with marketers such as ourselves …[58]

Information flows both ways, so problems overseas can cause questions to be asked here in Australia. As the political debate about GM food intensified internationally, producers and suppliers in Australia began to question the implications and future of the technology for them and the local economy. The international market for gene technology appeared uncertain and for many it was unclear whether they would benefit or suffer from using, or indeed avoiding GMOs and GMO products. This created greater awareness, and spurred debate about the technology and its use in Australia.

It should not be forgotten that, just as many gene technology companies act in a multinational capacity, so do lobby groups and non-governmental organisations.

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[56] Ed., 'Monsanto Won't Commercialize Terminator Gene' *The Wall Street Journal* October 5 1999, p A4.

[57] Verfaillie H , "A New Pledge For A New Company' (2001) *Executive Speeches* **4**:15:10-13.

[58] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, 2000, para 6.133. ,

Such groups disseminate messages to an international audience, using examples of mismanagement elsewhere as an illustration as to why local industry should not be trusted.[59]

The BSE problem in Europe was referred to continually in the Australian media,[60] and in Parliament[61] as an example of the fallibility of 'corporate science' and of the derision with which public concerns were treated until 'it was too late'. Similarly, international lobbying and campaigning made terminator technology a topic of debate here in Australia. It was a press favourite, and was mentioned in most stories dealing with gene technology.[62] Terminator technology and Monsanto's approach to public concerns about it, were also cited in Parliament and within Parliamentary inquiries as justification for governmental intervention in industry activity.[63]

The increasing domestic discourse ensured that gene technology became a political issue, which saw international lobby organisations giving way to an increasing number of local special interest groups. GeneEthics [see 3.2], which in

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[59] See for example the websites of: Greenpeace True Foods Campaign, <http://www.greenpeace.org.au/truefood/index.html> (20/12/02); Australian Consumers Assosciation <http://www.choice.com.au/articles/a101373p1.htm> (20/12/02), Australian Gene Ethics Network <http://www.geneethics.org/> (20/12/02); Oxfam and Greenpeace Farming Solutions, <http://www.farmingsolutions.org/> (20/12/02); Genetic Resources Action International, <http://www.grain.org/updates/index.cfm> (20/12/02); ETC Group (RAFI) <http://www.rafi.org/main.asp> (20/12/02).

[60] Ed., 'Genetic Crops Reaping Public Distrust' , *Herald Sun*, 19/11/98, p 4; Dupleix, J, 'Food Fiends', *Sydney Morning Herald* 20/05/1996 pp GL1, 8; Ellingsen P, 'Death And Devastation Down On The Farm', *Sydney Morning Herald*, 30/3/1996, p.33, Ed., 'Consumer Groups Upset Over Skewed Food Review', *The Australian* , 07/07/98, p 14; Reeves E, Messing with the Harvest, *The Mercury*, 9/6/1999. p 39

[61] see generally, *House Hansard*, pp 19449, 19470; *Senate Hansard*, pp 18855,19304, 20454

[62] For instance see, Smith D, 'Beans Means Genes' *Sydney Morning Herald*, 17/07/1998, p 11 ; Reeves E, Messing with the Harvest, *The Mercury*, 9/6/1999, p 39.

[63] "So we have the situation where gene technology has the ability to affect the production of food worldwide. For the first time we will see companies, through the use of gene technology, being able to control the production of food — and I believe that is immoral." Harris L, 'Gene Technology (Consequential Amendments) Bill 2000 …: Second Reading', *Senate Hansard*, 7/111/2000, p 19300 ; see also Joint Standing Committee On Treaties, *Australia's relationship with the World Trade Organisation*, Commonwealth of Australia (AGPS), Canberra, p 5 ; Community Affairs References Committee, '*Gene Technology Bill 2000*, Discussion, (Hobart, 23 August 2000), Transcript, Commonwealth of Australia, Canberra, 2000, p 199.

1995 was the only major Australian based lobby group to take an active interest in food and agricultural genetics issues, was to be joined by a much broader ground base of specialist non-governmental organisations. In 1997 the Australian Consumer's Association (ACA) joined Australian GeneEthics in gene technology specific lobbying and public interest activities. The ACA called for greater transparency in gene technology – with a particular emphasis on food.[64] These two bodies (GeneEthics and ACA) lead public interest activities in their respective areas, lobbied government and sought to increase public awareness of and interest in gene technology issues.[65]

3.3 THE INCEPTION OF A NATIONAL REGIME (1997 TO 1998)

The increased attention on gene technology and lack of intergovernmental action caused concern in some areas of government, particularly within the agricultural and industry portfolios. The Agriculture And Resource Management Council Of Australia And New Zealand (ARMCANZ) was particularly worried that Australia would lose out on the benefits of gene technology because of the legal and political environment. In August 1997 the Standing Committee on Agriculture and Resource Management (SCARM) of ARMCANZ reported that:

> in the absence of regulation, commercialisation of GMOs is being delayed or abandoned, and some research activities are on hold or research investments are not being made.[66]

It put this lack of development down to an:

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[64]Renouf C, 'Spilling The Gene Beans', *Choice Magazine*, 1/2/1997, pp 16-17. The online campaign began in 1998 with a large portion of the Association's website dedicated to this cause . See <http://www.choice.com.au> (7/12/02) see Wynhausen E, 'Consumers Clamour for Control' *The Weekend Australian*, 20/2/1999, p 199.

[65] Polya R, *Genetically Modified Foods-Are We Worried Yet?,* Report of Science, Technology, Environment and Resources Group, Australian Parliamentary Library, 1999 (e-version), <http://www.aph.gov.au/library/pubs/cib/1998-99/99cib12.htm> (12/03/02)

[66] ARMCANZ, *Regulation of Gene Technology*, Report to the Standing Committee on Regulation of Gene Technology, Australian Government Department of Agriculture, Fisheries and Forestry, 1997 : <http://www.affa.gov.au/docs/operating_environment/armcanz/gene/index.html> (12/2/02)

> ad hoc patchwork of agencies faced with ill defined powers and often reluctant responsibility for implementing new modes of regulation.[67]

According to SCARM this was creating uncertainty in among researchers, investors, industry and the community. It argued that research and development could only continue with 'a clear regulatory pathway that provides maximum security for research and commercial initiatives'. It also emphasised that a regulatory system should 'provide assurance to consumers and distributors of GMO products through appropriate risk management system'.

The regime proposed by SCARM and approved by the Agriculture and Resource Management Council of Australia and New Zealand was largely identical to that proposed by the 1992 Commonwealth-State Consultative Group on Genetic Manipulation [see 3.1.2]. Its underlying principles were to:

- provide a robust, responsive and evolving regime in the face of rapidly evolving technologies
- provide the necessary assurances to consumers and distributors of GMO products, particularly by protecting against unwanted public health and environmental outcomes
- provide a clear regulatory pathway for innovation and product development, with timely assessments of research and commercial initiatives, a consistent regulatory approach across government and low compliance and administration costs
- control the importation of GMOs
- not inhibit innovation and trade involving gene technology products.[68]

Following the August 1997 ARMCANZ meeting all state and territory governments, the Commonwealth and the CSIRO agreed to consider the need for a national framework for the regulation of gene technology.[69] In October 1997 the governments declared their intention to adopt a national system which would involve:

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[67] *ibid.*

[68] *ibid.*

[69] Joint Statement of by Commonwealth Ministers Moore, Anderson and Hill, (30 October 1997. See, <http://www.isr.gov.au/media/archive/october97/327-97.html> (12/12/02).

- the amendment of current legislation and introduction of new legislation to ensure uniformity and compulsory compliance;
- the establishment of a Gene Technology Office to administer a national regulatory system which will ensure that comprehensive analysis and risk assessment are undertaken before GMOs are released;
- the commencement of consultations with the public and the State and Territory Governments; and
- the establishment of an interim Gene Technology Liaison Committee to provide advice on urgent issues that could not be addressed under the existing regulatory systems.[70]

To pursue the adoption of the new regime a Commonwealth-State Consultative Group on Gene Technology (CSCG) was formed.[71] Over the next year the CSCG sought advice from the whole of government. This included State and Federal agencies responsible for health, environment, agriculture, industry and primary production. Once completed, (late 1998) the Government undertook broader consultations with stakeholders, the public and industry.[72]

The result of these consultations was the recommendation by the CSCG for the implementation of a comprehensive regulatory system for the oversight of gene technology with legal force in each jurisdiction of Australia. In November 1998 the CSCG drafted a proposed regulatory system and submitted it in the form of a report for public consultation.[73] The report requested views 'about the broad policy principles that might underpin the new regulatory scheme', which were then used to develop the 'operational details of the new regulatory system'.[74] The

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[70] *ibid.*

[71] Dept. Health Archive, *op cit* 4.

[72] Bodies consulted included: universities; consumer groups; environmental organisations; health professionals; the gene technology industry; retailers; the food industry; and primary producer groups. Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra., p 36.

[73] Commonwealth State Consultative Group on Gene Technology (CSCG) *Regulation of Gene Technology*, Commonwealth of Australia, AGPS,1998.

[74] Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000, paras 1.10-1.11.

report was followed up with face-to-face public consultations throughout Australia.[75]

3.4 AUSTRALIA LABELS SUBSTANTIALLY EQUIVALENT FOOD (DECEMBER 1998)

As the CSCG consultation process continued so too did the level of public interest – and apprehension – about gene technology increase. Whilst the international and domestic debates were a major factor in the increasing awareness and concern among Australians, it was the decision of a federal agency to meet and discuss the regulatory approach to the technology which would ultimately serve to thrust the technology into the public spotlight.

In 1998 the Australia New Zealand Food Standards Council – a body of health ministers from both of these nations – met to consider whether or not GM foods should be labelled or be classified as 'substantially equivalent' to conventional products. The meeting attracted a great deal of media interest after it became clear that the Council was not just considering the labelling of future products but *existing* ones too[76] Most Australian had believed GM food to be a foreign issue, as the technology had not yet reached local markets. The labelling decision revealed that, in fact, GM products *did* exist in local markets, *were* unlabelled and would remain so until, or if, labelling laws came into effect. Poyla describes the concerns at the time:

> [m]ost GM foods already in the market place have not been assessed ... Although it is thought that there are hundreds of food

[75] *ibid.*

[76] "Increased media coverage in Australia was triggered by the December 1998 decision of the Australian and New Zealand health ministers, the Australia New Zealand Food Standards Council (ANZFSC), to amend Standard A18 of the Australian Food Standards Code. ANZFSC insisted that 'substantially equivalent' genetically modified (GM) foods should be labelled, as well as the non-equivalent foods already stipulated in the Standard. The concept 'substantial equivalence' is designed to enable the same food safety regulations that apply to conventional foods and ingredients to be applied to GM foods assessed as 'substantially equivalent'. Having asked ANZFA (Australia New Zealand Food Authority) to provide a definition for GM food, as well as labelling amendments, ANZFSC will meet in July 1999 to consider ANZFA's drafts." Polya R, *Genetically Modified Foods - Are We Worried Yet?* Science Technology, Environment and Resources Group Current Issues Brief No.23, Australian Parliamentary Library, Canberra,1999, p4.

> products involved … Foods include products containing GE ingredients such as soybeans, canola, corn and potato in foods such as sauces, bread, pasta and confectionary. Concerns arise because of the lack of regulation of such foods in the past as well as uncertainty about how many GE ingredients are in foods on sale in Australia and what those foods might be. … In late March, ANZFSC gave permission for such foods to remain on sale pending assessment; giving rise to alarm by those already uneasy about GM foods.[77]

The lack of public awareness about existing GM derived products in the market was presented by the media and opponents of the technology as an industrial campaign to impose GM foods on an unsuspecting public.[78] Intense industry lobbying to maintain the doctrine of substantial equivalence did little to assist the matter. [79] One newspaper warned:

> this is just the beginning … a number of transgenic foods … with no announcement, no approval from any government organisation, no mandatory health or safety checks, and no labelling, have been quietly infiltrating Australia's supermarkets.[80]

Some argued that the public had been subject to a 'huge experiment', for which public consent should have been provided, because gene technology 'touches all of us in the most intimate and fundamental way - it's about who decides what we

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[77] *ibid.*

[78] "Your food may contain genetically modified soy beans. This food of the future has moved from paddock to plate with little debate. "; Hudson F, 'Chips That Are Fishy', *Herald Sun*, 05/11/1997, p 19, "Do you know what you're eating? Chances are you don't have a clue. genetically modified food is already stocking supermarket shelves, sparking debate on how informed consumers need to be about what they are eating." Watt A, 'Future Food', *Courier-Mail*, 29/7/1998, p 28; "Ingested any "gene beans" recently? That's a trick question; you're unlikely to know or to be able to tell." Ripe C, 'Tricky keeping track of genes in your beans', *The Australian*, 3/3/1998, p 14; also Ed., 'Genetic Crops Reaping Public Distrust', *Herald Sun* , 19/11/98, p 41, Hooper N, 'Consumers Bite Back at Genetically Modified Food', *The Age*, 10/9/1999, p 92.

[79] Cummins K , 'GM Debate May Leave Sour Taste', *Australian Financial Review*, 20/06/2000, p 58 ; Ed., 'PM Blocks Gene Food Rules' *The Advertiser* , 21/10/99, p 1

[80] Ed., 'Genetic Crops Reaping Public Distrust', *Herald Sun*, 19/11/98, p 41

eat, about the safety and the security of our food supply'.[81] Whilst there was genuine concern about the risks of GM food, most anger was firmly placed at the feet of those who had 'surreptitiously' introduced the products.[82] As one reporter reflected:

> [i]f all food containing genetically modified materials were to be labelled, as you would imagine it would if "enabling consumers to make informed choices" was paramount, there would be some extra costs to farmers and manufacturers.
>
> And labels might inhibit export to nations that didn't want GM foods. It might inhibit commerce if consumers decided they didn't want to buy foods so labelled. From the industry point of view, the most suitable approach may well have been to slip GM foods into the country without labelling and without informing consumers. That's what they did.[83]

The first company to respond to the sentiment was a small health food company, Australian Natural Food Holdings (now So Natural Foods Australia Ltd) which declared its intention to release its products under a 'GMO-free' label in 1998.[84] The company argued that they would label its products as such because they, 'decided the consumer had a right to know and a right to choose'.[85] The move angered industry groups, who publicly criticised the company, sent it letters and

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[81] "But this huge experiment is not just a debate about a new crop, farmers' incomes, or even biological pollution, important as they may be. It is a debate that touches all of us in the most intimate and fundamental way - it's about who decides what we eat, about the safety and the security of our food supply." Hills B, 'Guess What You've Been Eating' *Sydney Morning Herald*, 12/12/1998, p 1.

[82] "it is a 'basic contravention of citizen rights' not to label food and give consumers choice about whether to buy it", Dunlevy S, 'When a Sweet Tomato's Not Really a Tomato', *The Daily Telegraph*, 30/7398, p 9 ; `"It's not a safety issue we're talking about, it's a question of whether people have a right to know what they're eating … in most cases now we don't know the components of what we're eating", Watt A, 'Future Food', *Courier-Mail*, 29/7/1998, p 28 ; see also Ed., 'Genetic Crops Reaping Public Distrust', *Herald Sun* , 19/11/98 , p 41, ; Reeves E, 'Messing With The Harvest', *The Mercury*, 9/6/1999. p 39 ; Ragg M, 'Time to Find a New Recipe', *Sydney Morning Herald*, 25/06/1999 ; Ed., 'Genetic Crops Reaping Public Distrust', *Herald Sun* , 19/11/98, p 41 ; Cummins K, 'GM Debate May Leave Sour Taste', *Australian Financial Review*, 20/06/2000, p 58 .

[83] Ragg M, 'Time to Find a New Recipe', *Sydney Morning Herald*, 25/06/1999, p 15.

[84] Smith D, 'Beans Means Genes' *Sydney Morning Herald*, 17/07/1998, p 11; Bolt C , 'Free From Transgenics Label Not So Good', *Australian Financial Review*, 28/09/1997, p 20.

[85] *ibid.*

lobbied supermarkets not to carry its products.[86] The Australian Food Council was particularly vocal, arguing that differential labelling of 'substantially equivalent products' simply 'serves to reinforce prejudices that are unfounded', [87] and 'reflects a lack of understanding of the technology'.[88] However, the press and consumer groups were sceptical:

> [t]he arguments of the Australian food industry against giving consumers this sort of choice would be familiar to those who remember its opposition to the introduction of date-stamping, listing ingredients on labels, or any other consumer safeguard : you can trust us to make sure your food is safe, labelling would just mislead the consumer, it would be impossible to police, some packages would not have enough room for the extra wording. Seriously.[89]

The labelling issue was a major catalyst for community debate about gene technology. It provided a springboard for opponents of GM and remained a 'potential stick which the consumer and environmental movements [could] wield' about all aspects of gene technology, not simply food.[90]

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[86]Bold C, 'Soy pure labels rile food giants' *Australian Financial Review*, 22/04/1997, p 8 ; Bolt C , 'Free From Transgenics Label Not So Good', *Australian Financial Review*, 28/09/1997, p 20.

[87]"The AFC considers that kind of advertising unfortunate,' [the AFC executive] said. 'It is comparative advertising which implies differences in a product where none exists.' Mr Hooke said the AFC, which represents major food manufacturers, was not trying to impose its will on an individual company but rather stop consumers developing unwarranted prejudices against genetically modified foods.' We are trying to do what's best for the industry,' he said." Bold C, 'Soy Pure Labels Rile Food Giants' *Australian Financial Review*, 22/04/1997, p 8;

[88] Smith D, 'Beans Means Genes' *Sydney Morning Herald*, 17/07/1998, p 11; The company continued nonetheless and the brand became the fastest growing in the country and is now the largest manufacturer of whole soy bean beverages and food. Hills B, 'Guess What You've Been Eating' *Sydney Morning Herald*, 12/12/1998, p1 ; Currently listed as 'So Natural Foods Australia Limited (SNF.AX)', Company data from ASX, As of 7-Jan-2003, see <http://www.asx.com.au> (6/01/03).

[89] Hills B, 'Guess What You've Been Eating' *Sydney Morning Herald*, 12/12/1998, p1.

[90] *ibid.*

3.5 THE RISE OF STAKEHOLDER GROUPS (1998 ONWARDS)

As noted above, only one citizen group (GeneEthics) was active at the time gene technology was introduced into the international marketplace. Over the following years this lack of sectional interest in gene technology changed dramatically with a vast number of institutional actors becoming involved in lobbying and information dissemination activities. The most notable rise in stakeholder interest in gene technology occurred from 1998 onwards. This is most probably due to the labelling events outlined above and also the inception of the government's consultation about a possible gene technology regime under the aegis of the CSCG. The Emergence of these groups illustrates the transition from a rather disinterested population to a highly active, involved, highly concerned one. Stakeholder groups are formed in response to heightened levels of concern about a subject matter and simultaneously perpetuate even higher levels of concern about that subject matter. There was a radical alteration of the socio-political landscape in a relatively short time, as one citizen's group (GeneEthics) was joined by hundreds of stakeholder and interest groups. These groups included:

- *Environmental Organisations,* including Greenpeace Australia, which through its parent NGO Greenpeace international, began a campaign in 1997 calling for a moratorium on GM and labelling for GM food;[91] the World Wildlife Fund for Nature Australia, with particular emphasis on the environmental impact of GM plants;[92] Friends of the Earth Australia**,** focusing on 'field trials' and labelling;[93] the Environmental Defenders Office,[**94**] and, as noted above, the Australian Gene Ethics Network under the auspices of the Australian Conservation Foundation;

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[91] Coney S, 'Australasian Antipathy To Genetic Modifications', (1997) *The Lancet*, **349**:1610; Greenpeace archives to 1998 <http://archive.greenpeace.org/~geneng/> (12/03/02)

[92]WWFN began campaigning locally in 1999 for a 'halt to the commercial release of genetically modified tree species and stronger regulations for field testing, including a Biosafety Protocol within the international Convention on Biodiversity'. " Ed., 'Conservation Groups Call for Worldwide GM Forestry Ban', *Australian Associated Press,* Reuters, 9/11/1999, p 1.

[93] The EDO established a national campaign on genetics and food production in 1999 to focus attention on field trials and food manufacturers to adopt GE free policies 1999. Friends of the Earth Australia Annual Report 1999-2000 <http://www.foe.org.au/mainfiles/about_ar_99_00.htm> (24/12/02)

[94]Edo Tas, *Newsletter (December 1999)*, Environmental Defenders Office, Hobart, 1999, p 3.

- *Gene Technology Specific Networks*, including the National Genetic Awareness Alliance[95] and GE Tasmania;[96]
- *Consumer Groups*, including the Australian Consumer's Association; Consumer Food Network,[97] Food Intolerance Network of Australia;[98] the Consumers' Association of South Australia Inc;[99] Canberra Consumers Inc;[100] and Consumer Food Network of the Consumers' Federation of Australia;[101]
- *Local Seed Groups*, including The Heritage Curator Seeds Association and Seed Saver's Foundation[102] and the Digger's Club[103] dedicated to using non-patented, non-GM seed;
- *Farmers*, particularly organic farmers represented by the Organic Federation of Australia,[104] who declared their entire organically certified crop to be GM free. Other organic bodies that campaigned during this period against genetic engineering were the Bio-Dynamics Tasmania NT Bio Dynamic Network.[105] There was also some debate among

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[95]Submission 17 to the Senate Committee
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02)

[96]GE Free Tasmania Website is at <http://www.green.net.au/gefreetasmania/> (20/12/02) , Submission 35 (GE Free Tas) to the Senate Committee :
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02)

[97] Ragg M, 'Altered Foods Rules Must Have Teeth', *Sydney Morning Herald*, 30/07/1999 p 3.

[98]Food Intolerance Network of Australia, *Failsafe 13*, Newsletter of the Food Intolerance Network of Australia, October 1999 : <http://www.fedupwithfoodadditives.info/FAILsaf13.html>

[99] submissions 9,11,50 to the Senate Committee :
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02)

[100] *ibid.*

[101] *ibid.*

[102] Seed Saver Network. "We have been making critiques of the kind of breeding that GM companies pursue since 1995 in radio interviews and on GM laws in our newsletter" … other issues they have lobbied on include 'ecological dangers of the GM crops', terminator technology, 'genetic engineering and patents on life', especially with relation to the third world, GM foods, labelling, Email Correspondence from Jude Fanton, Director, The Seed Savers' Foundation, 9/01/03 21:06, on file with Author.

[103] "[T]he Diggers' Club seed business from a property on the Mornington Peninsula south of Melbourne. The club has 35,000 members, all of them committed to preserving biodiversity, conserving heritage varieties, and propagating "open pollinated" plants whose seed can be saved and grown." Hills B, 'Guess What You've Been Eating' *Sydney Morning Herald*, 12/12/1998, p1.

[104] Incorporated in March 1998, see Kinnear S, *Organic & Biodynamic Farming Background Paper*, available at <http://www.ofa.org.au> (22/10/02).

[105] Submissions 3 and 24 to the Senate Committee :

conventional farmers. Although this tended to relate to whether markets were receptive to GM foods, it reflects that community concerns were impacting in this sector as well;[106]

- *Political Parties.* The Democrats,[107] the Greens and the Natural Law Party[108] all led specific campaigns citing the risks of genetic engineering;
- *Insurers.* Whilst this group did not lobby in any way, their risk perceptions are relevant because they were often used to back arguments for anti-GMO lobbyists. The Insurance Council of Australia concluded that 'In our view liability insurers would be cautious when considering GM products and more needs to be known about the potential risks. The unforseen risk at this stage may be too high';[109]
- *Peak Medical Bodies,* including the Australian Medical Association and the Public Health Association of Australia, particularly in relation to the efficacy of the testing process;[110]

<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02)

[106] Cummins K, 'GM Debate May Leave Sour Taste', *Australian Financial Review*, 20/06/2000, p 58 . ; Ed., 'Council Calls for Genetic Crop Ban.' *The West Australian*, 20/3/2000 p 9 ; Ed., 'GM Fears Used As Lever', *The Land.* 16/3/2000, p 39 ; Ed., 'Non-GMO Maize "Window", Then…' *The Land, 16/3/2000,* p 25 ; Wynen E, *Genetic Engineering And Agriculture: Australian Farming At The Crossroad*s, Report of the Economics, Commerce and Industrial Relations Group, Commonwealth Library, Canberra, 1999.

[107]Mitchel B, 'Democrat Proposal to Green Australia' *The Age*, 10/09/1998, p 8; Submission No. 28 (Senator Natasha Stott-Despoja) to House Inquiry :
<http://www.aph.gov.au/house/committee/primind/gtinq/subs.htm> (20/12/02)

[108]Submission No. 45,(Natural Law Party), Submission to, Commonwealth House of Representatives, Inquiry into primary producer access to gene technology, 1999 :
<http://www.aph.gov.au/house/committee/primind/gtinq/subs.htm> (3/12/02).

[109]The ICA was explaining the position of the industry after GeneEthics claimed to the Committee that Swiss Reinsurance would not underwrite GM trials. "With the lack of a suitable product history it is relatively easy to see why insurers would be cautious. This is well founded given other man-made disasters this century involving products for human consumption … In our view liability insurers would be cautious when considering GM products and more needs to be known about the potential risks. The unforseen risk at this stage may be too high." Drummond R, *Insurance Council of Australia Advice to, House of Representatives Standing Committee on Primary Industries & Regional Services, 1999,* <http://www.aph.gov.au/house/committee/primind/gtinq/sub83-e.pdf> (20/12/02)

[110] The call to streamline GM food production from 'paddock to plate' provoked alarm from Australian Consumers Assosciation and Australian Medical Assosciation. They argued GM foods had been introduced 'without regard for full and independent safety evaluation, or full and adequate public consultation or rigorous assessment of health impacts' [Sutherland L, 'Fears over Frankenstein Food' *The Sunday Tasmanian.* 23/3/1999. p 9]. See also Ragg M, Altered foods rules `must have teeth' *Sydney Morning Herald,*

- *State Governments*, particularly Tasmania, which declared a moratorium on GMOs, citing the 'need to be certain GMOs won't pose a risk to our health, or our environment, or our agriculture';[111]
- *Local Councils*, many of which attempted to declare themselves GM free zones under local planning laws (the validity of which has not yet been tested);[112]
- *Food Companies.* In 1997 the first food company in Australia undertook to remove GM ingredients from its products (Australian Natural Food Holdings [see 3.4]). By 2000 a large number of food producers had removed GM ingredients from their products and/or lobbied government to label food and/or allow for GE free zones.[113]
- *The Media.* One of the most influential social actors, took a keen interest in the development of gene technology in Australia, particularly post 1998, with many of the news being negative or reflecting a lack of trust in those in control of gene technology.[114]

30/07/1999 p 3 ; Martin C, 'Health Risk Claim From GM Plan', *The Australian Financial Review*, 7/72000, p. 10; Smith D, 'Safety-First Approach, But No Guarantees' *Sydney Morning Herald*, 24/07/2000, p 4.

[111]Darby A, Metherell M, 'GM Crops Are Pests, Tasmania Declares', *Sydney Morning Herald*, 21/07/2000, p 3 ; Food Industry Council of Tasmania, *The Production of Genetically Modified Foods in Tasmania*, Report to the Department of State Government Tasmania, Hobart, 2000.

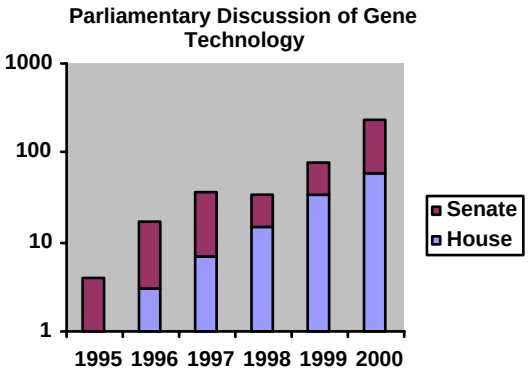
[112] A list of councils which have declared themselves GE free may be found at The Friends of the Earth Network (NSW) <http://www.sydney.foe.org.au/gene_ethics/councils.htm>, see also Marickville Council, *Genetically Modified Foods*, Discussion Paper (April 2001), pp 13-15, <http://www.tec.nccnsw.org.au/member/tec/projects/upload/council.pdf> (3/12/02).

[113]These included Goodman Fielder, Sanitarium Health Food Company, Heinz Watties Australia, Arnotts, George Weston Foods, Dairy Farmers, Cadbury Schweppes, Mars Confectionary of Australia, Kellogg Australia, Master Foods of Australia, Lactos, King Island Dairy Company, Classic Foods, Vineyards Association of Tasmania, Tasmanian Apple and Pear Growers Association, Salmon Growers Association of Tasmania, Vitasoy International Holdings Ltd. See Hooper N, 'Consumers Bite Back at Genetically Modified Food', *The Age*, 10/9/1999, p 92 ; Ed., 'Organic market Challenge', *The Sunday Tasmanian*, 16/7/2000, p 3 ; Verzola R, *The Genetic Engineering Debate*, BiotechInfoNet, Working Document 1.02, <http://www.biotech-info.net/verzola_GE_debate.pdf> (28/11/02).

[114]Poyla notes that "Increased media coverage in Australia was triggered by the December 1998 decision of the Australian and New Zealand health ministers, the Australia New Zealand Food Standards Council (ANZFSC), to amend Standard A18 of the Australian Food Standards Code.", *op cit 153.* In a follow-up Poyla notes "It is unfortunate that the GM press generally discusses 'should we' or 'shouldn't we', when we 'are' clearly living in a GM world, rather than devoting more space to the implications of the proposed regulations and alternative regulatory options.", [Polya R, *Genetically Modified Foods - Are We Worried Yet?* Science Technology, Environment and Resources Group Current Issues Brief No.23, Australian

- *The Parliament.* Debate in Parliament increased exponentially during this period [see Figure 2] leading to both House and Senate inquiries into the introduction of the technology.

FIGURE 2



The point of examining the increase in stakeholder and interest groups is not to verify the risks posed by gene technology, nor the supposed ignorance of these various active publics. Rather, it reveals a dramatic escalation of socio-political concern over gene technology and the belief among much of the population that its introduction needed, at the least, to be debated. The implications of such a shift will be examined at length below [see 13.1-13.3]. However, it is worth noting here that these stakeholder groups exert a real influence over both the behaviour of institutional actors, such as industry and government, and the way the constituencies they represent think and behave.

3.6 CONSENSUS CONFERENCE (MARCH 1999)

In early March 1999 the Australian Museum hosted the *Consensus Conference on Gene Technology in the Food Chain* (the Consensus Conference).[115] The conference was initiated by the Australian Consumers Association in response to the growing public sentiment towards gene technology, the lack of adequate

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Parliamentary Library, Canberra,1999, p 44]. For summary of media responses to Biotechnology, see Cormick C, *Bio-Media Forum: Paper Presented To The Brisbane Instutute* Date: 08 June 2000 <http://www.brisinst.org.au/resources/cormick_craig_survey.html>; also Emmerson G, *Gene Cuisine: Genetically Modified Foods*, Research Bulletin No 3/97, Queensland Parliamentary Library, Brisbane, 1997.

[115] 10th March 1999; The Australian Museum, *Lay Panel Report*, Australian Consensus Conference on Gene Technology in The Food Chain (12/3/1999), The Australian Museum 1999.

debate, and the forthcoming Gene Technology Bill discussions.[116] Although not initiated by government it would come to receive financial and logistical support as well as an ancillary role within the drafting process [see 14.3.1].

The Consensus Conference was chaired by two panels, one of citizens (the Lay Panel) and the other of experts in gene technology (the Experts Panel). The Experts Panel comprised of representatives of various industrial, private and public organisations who dealt with gene technology. The Lay Panel set out various questions to which different members of the Expert's Panel answered and debated. The Citizen's Panel deliberated on the evidence presented and gave a report of their findings.

The views of the Lay Panel provided a good indication of how an informed public might respond to the introduction of gene technology. Their report was prepared only after they had consulted with experts and had the technical and scientific aspects of the technology explained to them. Senator Stott-Despoja described the result of the Consensus Conference thus:

> [t]he conference's report is one of the most comprehensive and clearest articulations of public opinion on GMOs to date in this country. The success of the conference demonstrates that genetic issues belong in the public arena.[117]

The Lay Panel expressed concern over the potential impact of gene technology on human health and the environment. However, they noted that there was a lack of publicly accessible trustworthy information about the technology from which the community could make informed decisions. They also expressed a concern that decisions were being made too quickly and without public consultation. Indeed, the very first finding of that conference was that the institutions responsible for gene technology in Australia 'are currently not serving community interests'[118]

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[116] *ibid.*

Stott-Despoja N, 'Genetically Modified Food Gene Technology: Human Cloning', *Senate Hansard*, 22/3/1999, p 2965.

[118] Lay Panel Report, *op cit* 115, p 5.

and that 'multinational corporations have been allowed to decide the fate of GMOs'.[119]

According to the panel there was simply too little knowledge among the community as to the risks and benefits of gene technology and:

> [t]he decision making process is currently inaccessible and open to bias. Decisions by any regulatory body should take into account more than just science. [120]

The Panel further highlighted the right of people in a democracy to accept alternatives to the technology or indeed reject it outright. They argued that, beyond providing a democratic choice to citizens, GMO alternatives might also open new and lucrative markets. Consequently, the Panel recommended an independent assessment of the benefits that might accrue from adopting 'non-GMO alternatives' and the 'political, cultural, financial and environmental ramifications' of such a choice.[121] According to the Panel, this information needed to be made available to the wider public to ensure 'an inclusive decision-making process'.[122]

The Panel emphasised that environmental and human health should be of 'paramount concern in any decisions regarding gene technology'.[123] They urged further research into the risks of all gene technologies and the creation of prevention, preparation and liability strategies to deal with any possible risks caused by GMO applications.[124]

The Democrats would later propose that such a 'citizens jury' be transferred directly into the Office of the Gene Technology Regulator (OGTR).[125] This proposal was not adopted. Instead the Government promised to undertake another

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[119] *ibid,* p 6.

[120] *ibid.*

[121] *ibid* p 9.

[122] *Ibid.*

[123] *ibid* p 7.

[124] *ibid.*

[125] Despoja N, '*Gene Technology Bill* 2000 … ' *Senate Hansard*, 1/12/2000, 20460

consensus conference within the first year of the OGTR's operation.[126] This never occurred.

3.7 HOUSE INQUIRY (MARCH 1999)

On the 30th of March 1999, the *House of Representatives Standing Committee on Primary Industries and Regional Services* was referred an inquiry into how small and medium sized Australian enterprises might better access the benefits of gene technology.[127] The chairman of the Committee, Fran Bailey, argued that the inquiry was necessary to ensuring the best possible strategy for Australia to reap the benefits of the 'next great world wide revolution'.[128] She insisted that Australia could not 'afford to be left behind in this debate' but must 'benefit from advances in gene technology'.[129]

The Committee was charged by its terms of reference with investigating: the value and importance of both traditional and genetically modified varieties; the implications of the commercialisation of gene technology varieties; how to ensure access to gene technologies for Australian producers; and how to encourage local innovation.[130] The Committee was also asked to examine the appropriateness of 'current variety protection rights, administrative arrangements and legislation'.[131] Finally, the Committee was to explore 'opportunities to educate the community of the benefits of gene technology'.[132]

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[126] Interim Office of the Gene Technology Regulator, *Quarterly Report* (June 2000), Commonwealth of Australia (AGPS), Canberra, 2000, p 12.

[127] Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution – Primary Producer Access to Gene Technology*, Commonwealth of Australia (AGPS), Canberra, 2000.

[128] Bailey F, 'Fran Bailey Announces Inquiry Into Gene Technology', Media Release (30/3/99), <http://www.aph.gov.au/house/committee/primind/gtinq/Media1.htm> (13/4/02))

[129] *ibid.*

[130] *ibid.* p 4.

[131] *ibid.*

[132] *ibid.*

The House Committee held public hearings in Canberra, Perth and Melbourne and private discussions in Western Australia with public and private stakeholders.[133] The committee also advertised for and received submissions from all states and territories. Given its mandate it primarily consulted with, and received submissions from industry and producer parties [see 3.6]. A final report was produced for debate in the House on June 2000. The report, its recommendations and conclusions are discussed at 14.4.2.

3.8 THE MONARCH INCIDENT (MAY 1999)

From the outset, the alleged affect of GMO derived foodstuffs on human health dominated the public debate. However, the public concern about the impacts of gene technology was to broaden significantly subsequent to a report published as a letter in the prestigious scientific journal *Nature* in May of 1999.[134] It alleged that monarch larvae fed milkweed dusted with genetically modified pollen experienced lower growth and feeding rates and suffered higher mortality rates than those fed milkweed without modified pollen. The authors called for further investigations into the potential adverse affects of the genetically modified maize. The paper has received a great deal of scientific and academic attention and criticism and its findings and impact will be dealt with in greater detail later [see 8.3]. What is important is the immediate impact that paper had on the public psyche, as it was taken out of the academic context and published in popular press.

The public response to the paper was immediate and widespread. The monarch became a symbol of the anti-GM lobby and was regularly 'cut and pasted' into newspaper articles on the 'pros and cons' of gene technology.[135] The monarch even adorned the cover page of the *Australian Magazine* in an article questioning

[133] House Report, *op cit 1*, paras 1.8-1.9.

[134] Losey JE, Rayor LS, Carter ME, 'Transgenic pollen harms monarch larvae' (1999) *Nature* **399**: 214.

[135] Carey J, 'Imperiled Monarchs Alter the Biotech Landscape', *Business Week*, 7/6/1999, p 36. Pew Initiative on Food and Biotechnology, *Genetically Engineered Corn and the Monarch Butterfly Controversy*, Report of the Pew Initiative on Food and Biotechnology, University of Richmond, Washington, 2002. p 3.

the future of gene technology.[136] The popular science journal *New Scientist* declared 'America's famous monarch[s]' to be 'under siege' from a technology that 'appears to be poisoning' them.[137]

The monarch came to represent the impacts of human interference with the very structure of nature and remains a potent and enduring image in the public psyche about the impacts of gene technology on the environment. Just as the labelling debate acted as a 'potential stick' yielded against the gene technology industry, so too the monarch became the major tool in the arsenal of activist and lobbyists. The result was that the mainstream public came to perceive gene technology as having much broader repercussions, not just to the food they ate, but to the environment around them. This broadened the debate and placed a greater emphasis on need for environmental protections to be placed within proposed gene technology legislation.

3.9 19992-2000 BUDGET – BIOTECHNOLOGY AUSTRALIA AND THE INTERIM OFFICE OF THE GENE TECHNOLOGY REGULATOR

(MAY 1999)

Amid the growing controversy surrounding gene technology the 1992-2000 Federal Budget was released. The Commonwealth Government used this budget to clarify its position on gene technology by announcing funding for two new bodies, Biotechnology Australia and the Interim Office Of the Gene Technology Regulator (Interim OGTR). [138]

An additional $31 million was allocated to supplement the $250 million already dedicated to gene technology and research. This was designed to reinforce the

[136] Callaghan G, 'Seeds of Doubt', *Australian Magazine*, 3/7/1999, Cover, (article p 28).

[137] Kleiner K, 'Monarchs Under Siege', (1999) *New Scientist* **162**: 4.

[138] *BUDGET 1999-2000*, Budget Paper No. 2 - Budget Measures : Industry, Science and Resources, 11/5/1999. see also Commonwealth Biotechnology Ministerial Council, *National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 1999, p 8.

Government's 'very strong commitment to [the] industry.'[139] The additional funding was dedicated to establishing infrastructure for the management and promotion of gene technology in Australia through a central non-regulatory agency entitled 'Biotechnology Australia'. The new body was to 'assist the biotechnology industry to maximise its contribution to the Australian economy … [and] to advance developments and harness discoveries in this area'.[140]

Biotechnology Australia was designed to be a 'one-stop-shop', coordinating the effort of five Government departments.[141] Its initial mandate was to develop a national biotechnology strategy [see 3.14]. A Biotechnology Consultative Group, consisting of 22 members of the research community, industry, ethicists and nutritionists was formed to advise Biotechnology Australia and the Commonwealth on the development of this strategy. The role of this body is discussed at length later [see 14.3.2,0].

Whereas Biotechnology Australia was created to evidence the governments commitment to the industry the Interim OGTR was intended to reinforce the Government's commitment to:

> deliver increased assurances to the public about the maintenance of high standards of health and environmental protection, and

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[139]"We have established Biotechnology Australia in my department, and we have launched a comprehensive national biotechnology strategy, with initial funding of $30 million. Some $20 million of that will go to a new biotechnology innovation fund to help bridge the commercialisation gap in this industry. We are also working closely with the states, including joint funding for the Institute for Molecular Bioscience in Queensland and Bio21 in Victoria. We also helped 35 small biotech companies participate in Biotechnica Germany '99, which helped put our industry on the world stage. So we have a very strong commitment to this industry." Minchin, Sen Nick, Question without Notice: Biotechnology**,** 7 September 2000 Senate Hansard, p 17576

[140] The Honourable Peter Costello, MP Treasurer Of The Commonwealth Of Australia, 'On The Second Reading Of The Appropriation Bill (No. 1) 1999-2000', Delivered On 11 May 1999, Commonwealth of Australia, 1999.

[141]Department of Industry Science and Resources, Department of Environment and Heritage, Department of Agriculture, Fisheries and Forestries, Department of Health and Aged Care, Department of Education Training and Youth Affairs. See *BUDGET 1999-2000,* Budget Paper No. 2 - Budget Measures : Industry, Science and Resources, 11/5/1999

> streamlined approval processes with a clear pathway to market for industry.[142]

The Interim OGTR was to be a permanent office established in lieu of the enactment of a national Gene Technology Act. Until a full regime was put in place an interim office operate under the auspices of the Therapeutic Goods Authority. The Interim OGTR was still a non-statutory body and would operate under the GMAC guidelines with the GMAC continuing to serve as an advisory body to the Interim OGTR.[143] The interim office also oversaw public consultations toward the new regime[144] as well as contributing to the development of policy and regulation which would underpin that regime. The Government expected that a full fledged Office of the Gene Technology Regulator would be operational by July 2001.[145]

The 1999-2000 Federal Budget provided the government with an opportunity to make a very public statement about its willingness to intervene in the commercialisation of gene technology on behalf of both the industry and the public. In both cases the government was jumping the gun so to speak. The official announcement of Biotechnology Australia along with a formal statement about its role and mandate would only come the following year with the Biotechnology Strategy [see 3.14].

The pre-emptive nature of the Government's budget allocation and associated media releases was even more apparent with respect to the Interim OGTR. Whereas Biotechnology Australia was a non-regulatory departmental body which did not require Parliamentary approval, the Interim OGTR would only become effective with the enactment of the *Gene Technology Act* 2000 (Cth) (GTA/the

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[142]Therapeutic Goods Administration, *TGA News*, Issue 30 (September 1999), Therapeutic Goods Administration <http://www.health.gov.au/tga/docs/html/tganews/news30/cover.htm> (3/2/02).

[143] Wooldridge M, *New Safety Measures For Genetically Modified Products*, Media Release(MW80/99), 22 August 1999.

[144] Wooldridge M, *Public Forums To Encourage Community Comment On Gene Technology* Regulation , Media Release (31/1/2000 :
<http://www.health.gov.au/mediarel/yr2000/dept/mr20002.htm> (21/3/02).

[145]*ibid.*

Act). After the previous failed attempts to implement legislation; the substantial hurdles that had to be overcome to ensure national consistency; not to mention the uncertainty as to whether both houses of Parliament – particularly the Senate where the government was in minority[146] – would pass the Gene Technology Bill; there was simply no guarantee that the body being established was viable in the long term or would actually become a permanent office.

The fact that budget allocation preceded the formal establishment of both these bodies is not extraordinary –funding is the first step to the creation of most organisations. Nevertheless, the major emphasis on promoting these bodies within Parliament and governmental press releases indicates a sense of urgency within Government to put its policies into the public domain. It also suggests that government was responding to concerns within both industry and the community about the lack of government led dialogue on and oversight of the technology. Subsequently the budget was utilised by the government as an avenue to declare its commitment to reform existing structures and become more involved in gene technology generally.

3.10 TRACING PUBLIC OPINION – THE SECOND AUSTRALIAN SURVEY ON ATTITUDES TO GENE TECHNOLOGY (JULY 1999)

One of the first things that Biotechnology Australia did to inform itself about public sentiment towards gene technology in pursuance of its mandate to develop the National Biotechnology Strategy [see 3.14] was to commission a national survey into attitudes on gene technology. This survey was undertaken in mid 1999, market research firm Yann Campbell Hoare Wheeler (YCHW) - on behalf of Federal Government – undertook a review into the perception of gene technology.[147]

[146] Bartlett A, A Squeeze on the Balance of Power: Using Senate `Reform' to Dilute Democracy, Australian Federal Parliament Papers 1999 : <http://www.aph.gov.au/Senate/pubs/pops/pop 34/c09.htm> (7/12/02)

[147] Yann Campbell Hoare Wheeler, *Public Attitudes Towards Biotechnology Nationwide For Biotechnology Australia.* Research Report, Biotechnology Australia, Melbourne, 1999. <http://www.biotechnology.gov.au/library/content_library/BA_pYCHW.pdf> (7/12/02)

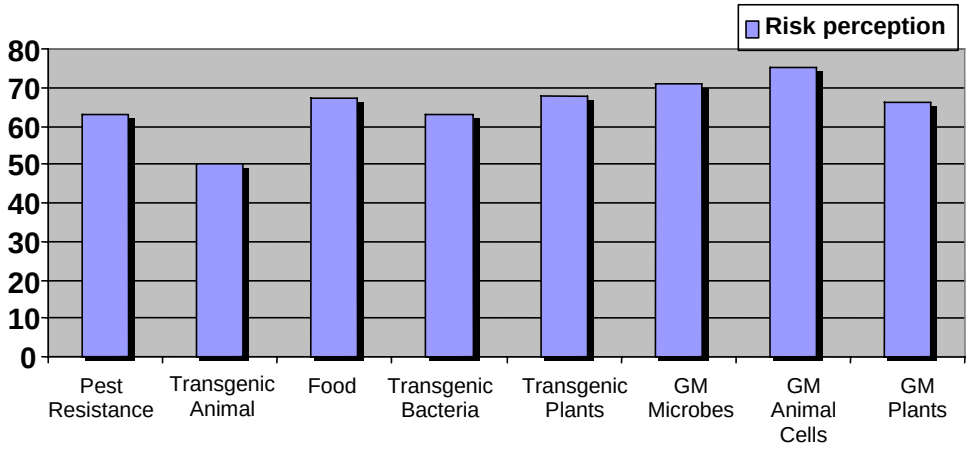

FIGURE 3

Unlike the 1995 CDIST study [see 3.2], YCHW participants were not presented with 'potential risks', but were asked instead how 'risky' they perceived different types of gene technology. This was perhaps a more accurate picture of actual risk perception, as those questioned were not being 'educated' to possible risk scenarios. Rather, their risk perception had been garnered from broader associations with gene technology (sources such as the media, private discourse, public education etc).

Like the 1995 CDIST study, most participants viewed gene technology as being of public benefit and worthy of encouragement. However, participants simultaneously described all gene technologies as 'high risk' (on a risk perception scale) [see Figure 3, Figure 1].[148] This equated to a low acceptability threshold, because despite realising the potential public benefits from the technology, they concurrently believed that the 'high risks' it posed could not be sufficiently attenuated by those in charge. The researchers concluded that;

> Most participants were suspicious of biotechnology … A few participants noted the social and health benefits that could arise from biotechnology … Cynicism, however, was more prevalent than the perceived benefits with most participants considering

[148] [pest resistant plants (63%), Transgenic animals with human genes (50% medical studies, 67% for human organs), food (67%), transgenic bacteria with human genes(63%) , transgenic plants with animal genes

> that private enterprise directs the development of these applications and is only driven by financial returns.[149]

3.10.1 POLITICAL AND CORPORATE RESPONSE TO PUBLIC OPINION (MID TO LATE 1999)

By late 1999, there was what the media termed, a 'growing crescendo' of 'consumer concerns about food with strange genes', entering the food supply without the public's consent or knowledge.[150] As can be seen above, this sentiment was driven by a combination of international and domestic events, the behaviour of various bodies, and the lobbying activities of various constituencies. Public awareness was also raised through involvement in participatory processes sponsored, or undertaken, by Government, such as surveys and through the regulatory consultations on the part of CSCG.

Governmental Response. The draft Gene Technology Bill was released in August 1999. The 'growing crescendo' of community concern over gene technology was evident in the way the new legislation was publicised and promoted. The Government emphasised that the Bill would mend the deficiencies in the current system but most particularly remedy the lack of public consultation on matters relating to gene technology. The Ministerial press release announcing the new Bill stated:

> The new measures [established under the proposed Act] … strengthen existing arrangements by providing a more rigorous, transparent and accountable decision-making system for the commercial release of genetically modified products …
>
> These new arrangements will help safeguard human health and the environment while allowing us to capture the maximum benefit of gene technology for the Australian community, industry and the environment …

(68%), transgenic animals with plant genes (68%), GM microbes (71%), GM animal cells (75%), GM plants (66%) *ibid.*

[149] *ibid.*

[150] Hooper N, 'Consumers Bite Back at Genetically Modified Food', *The Age*, 10/9/1999, p 92.

> There are substantial community concerns surrounding the introduction of GMOs into the market and I am confident the new measures will go a long way to allaying those concerns … Importantly, the new controls provide many opportunities for community input into decisions …[151]

The Government declared the proposed legislation would come into force by July 2001.[152] Debate on the Bill and domestic events would greatly increase public awareness of and involvement in, the gene technology debate during this period.

The Private Sector. The growing crescendo of community concerns also impacted on the private sector, albeit with mixed results. Some companies responded to the public backlash by announcing that they would begin the arduous process of product tracing and labelling.[153] In other cases, the public backlash served to entrench industry opposition to intervention and labelling.[154] For instance, the Executive Director of the Australian Food Council called the push for labelling, 'a clever campaign that is trying to scare the shit out of people'.[155] Others argued that consumer concerns were merely a product of 'ignorance',[156] 'fear'[157] and 'pig-headed opposition'.[158] When the Consensus Conference [see 3.6] berated industry and government for their handling of gene technology and called for more stringent regulation, the Executive Director of the Australian Supermarket Institute replied:

> [s]care campaigns show us the limits of democracy … The recent consensus conference on gene technology was anti-science, anti-knowledge. Galileo would have found the circumstances familiar. The final communiqué shows that the

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[151] Wooldridge M, *New Safety Measures For Genetically Modified Products*, Media Release (22/8/1999), MW80/99, Commonwealth Department of Health and Aged Care, Canberra, 1999.

[152] *ibid.*

[153] Ripe C,' Tricky Keeping Track Of Genes In Your Beans', *The Australian*, 3/3/1998, p 14

[154] Cummins K, 'GM Debate May Leave Sour Taste', *Australian Financial Review*, 20/06/2000, p 58 . ; Ed., 'PM Blocks Gene Food Rules' *The Advertiser* , 21/10/99, p 1

[155] Hills B, 'Guess What You've Been Eating' *Sydney Morning Herald*, 12/12/1998, p1.

[156] Ed., 'Biotechnology: A Challenge, Opportunity', *Courier Mail*, 30/10/1999, p 22.

[157] Ed., 'Modified Food Fear', *Herald Sun*, 16/10/99, p 19.

[158] Crawford D, 'Cash Crop Worth Risk', *Tasmanian Country*, 28 /7/ 2000, p 001

> conference was a waste of time. The participants were at best naïve.[159]

Such reactions – whether or not they were justified – broadened the gulf between the industry and public, exacerbated public discontent and fuelled the calls for strong regulatory intervention.

3.11 PROPOSED GENE TECHNOLOGY REGIME PUBLISHED (OCTOBER 1999)

In October 1999 the Commonwealth-State Consultative Group on Gene Technology (CSCG) [see 3.3] drafted a skeleton architecture of a new national gene technology regime. This proposed regime was based on the broad policy principles developed over the course of consultations with all levels of government, the private sector and the public. The proposed scheme was circulated in October 1999 in the form of an issues paper entitled 'Proposed national regulatory system for genetically modified organisms – How should it work?'. The CSCG extended an invitation for public comment on the issues paper, in response to which over 200 submissions were received.[160]

The CSCG, in collaboration with a newly formed Interim Office of the Gene Technology Regulator, then undertook face-to-face public consultations in each state and territory during November and December 1999. As a result the first draft Gene Technology Bill was released, along with a plain English guide explaining its provisions. A further round of consultations was undertaken upon this Bill at the end of 1999.[161]

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[159] *Gene Technology & Food*, Report of the National Science & Industry Forum, April 1999, Australian Academy of Science, Canberra, p 9.

[160] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra, p. 36

[161] Further details on the main issues debated at these fora are contained in the Explanatory Memorandum to the Bill.(Ibid., pp. 37-41)

3.12 MT GAMBIER (MARCH 2000)

In early 2000 a series of media exposés (the first in March) revealed that Aventis Crop Science had disposed of trial GM canola plants on a commercial tip in Mount Gambier South Australia.[162] Such action was contrary to GMAC guidelines. It was also revealed that the farmers who had grown the canola were not informed that it had in fact been genetically engineered.[163] Nor had local councils, neighbours or the public been informed of the existence of the crop trials.[164] Aventis later admitted that:

> the fact that we may not have used the terminology 'genetically modified organism' and included that in a written contact, I guess is where we may have missed the boat from the public perspective.[165]

Aventis, however, denied that farmers were ill informed,[166] that the GMAC requirements were necessary[167] or that breaches were in any way 'significant'.[168] Indeed, Aventis argued that investigating the impacts of the breach was simply **'**to waste more taxpayer's money'.[169] This 'dismissive' attitude caused 'the spotlight

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[162]Strong G, 'GM Crop Dumped At Tip'**,** *The Age* 25/3/2000, p 1 ; Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill* 2000, Commonwealth of Australia (AGPS), Canberra, 2000, Chapter 6; Miller C, 'Workers Spread Seeds From GM Trial', *The Age* 3/5/2001; Ed., 'Modified Foods Growing In Secret', *Sydney Morning Herald* 22/3/2000, p 2.; Metherell M, 'GM Crop Trial Breached Rules', *Sydney Morning Herald*, 14/8/2000, p 6.; Correy S, 'GM crops 2000: The Unmaking Of A Genetically Modified PR Campaign.', Background Briefing: Program Transcript (#42/2000 26th/11/2000)
<http://abc.net.au/rn/talks/bbing/> (8/07/02).

[163] It was further alleged that Aventis had not required farmers to implement the biosafety measures recommended by GMAC [Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill* 2000, Commonwealth of Australia (AGPS), Canberra, 2000, paras 6.113- 6.117] Strong G 'GM crop dumped at tip.' *The Age* 25 March 2000 pp 1 & 8 ; Strong G ' GM Police to Check Canola Sites' *Sydney Morning Herald* 23/08/2000, p 7.

[164] Correy S, 'GM crops 2000: The unmaking of a genetically modified PR campaign.' *Background Briefing – Program Transcript (#42/2000)*, 26/11/2000, <://abc.net.au/rn/talks/bbing/> (12/11/02).

[165] *ibid.*

[166] *ibid.*

[167] Submission No.61, pp.9-10 (Aventis), to the Senate Committee
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[168] Strong G ' GM Police to Check Canola Sites' *Sydney Morning Herald* 23/08/2000, p 7.

[169] *ibid.*

of controversy … [to swing] away from the corporation Monsanto to Aventis, and Aventis … managed to upset regulators, farmers, consumers and investors.' [170]

The GMAC[171] was also criticised by the media, public and Parliament for its handling of the Mount Gambier affair. Allegations against the GMAC about how it dealt with the Aventis breach included:

- facilitating an environment of secrecy surrounding the GM crops grown in the Mt Gambier and other trial areas, including failing to inform local government and farmers in the areas growing the crops of their existence;[172]
- tardiness in responding to complaints and informing complainants, the Government and public of action taken against Aventis;[173]
- keeping preliminary reports on Aventis' activities at Mt Gambier to the Federal Parliamentary Committee secret;[174] and
- responding to complaints about Aventis in a manner 'more akin to a lecture … than an inquiry into [public] concerns'.[175]

Perhaps the most dominant and widespread concern was the secrecy afforded to the trials by the GMAC. The situation was made worse when Aventis alleged that the GMAC was 'aware of breaches the company had made in the past and that it

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[170] Correy S, 'GM crops 2000: The unmaking of a genetically modified PR campaign.' *Background Briefing – Program Transcript (#42/2000),* 26/11/2000, <://abc.net.au/rn/talks/bbing/> (12/11/02).

[171] Although by this stage the GMAC was operating in conjunction with the Interim Office of the Gene Technology Regulator, the GMAC was generally seen as representative of the existing regime.

[172] *ibid*, paras, 6.125-6.129, Highfield J, 'Genetic Modified Crops Kept A Secret', *ABC News Online*, 27/3/2000, transcript at <http://www.abc.net.au/worldtoday/s113782.htm> (12/12/02)

[173] "The committee was very concerned to hear allegations earlier this year that Aventis (formerly AgrEvo) trials of herbicide tolerant canola in the Mount Gambier area of South Australia had breached GMAC guidelines. It is even more worried by the manner in which the IOGTR has investigated the alleged breaches, in particular its tardiness in completing its investigation. The IOGTR began its examination of the allegations on 24 March 2000 and, as at 18 May, the results of this examination had not even been forwarded to the Minister for Health and Aged Care, let alone been publicly released." Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution – Primary Producer Access to Gene Technology*, Commonwealth of Australia (AGPS), Canberra, 2000, , paras 7.17-7.18, see also Strong G, 'Seeds of Discontent' *The Age*, 16/06/2000, p 13.

[174] Strong G, *ibid;*. Mclucas S, '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 8/11/2000, p 19362.

[175] Strong G, *ibid.*

had not acted on them'.[176] It further claimed that, 'the only reason the GMAC and the Interim OGTR chose to act this time was because the issue had been made public'.[177] The finger pointing by Aventis, and a subsequent denial of the allegation by the Interim OGTR,[178] did little to stop claims of collusion between industry and government. Speaking on the floor of the Senate, Senator Stott-Despoja stated:

> [e]xamples of similar inadequate containment and notification of GM trials in Mount Gambier give further weight that GMAC's current 'behind closed doors' … regulation is both insufficient and inappropriate. It fuels distrust.[179]

The Organic Federation of Australia also condemned GMAC's approach.

> Secrecy is a huge issue. We have to get over this notion that these crops have to be grown in secrecy. It's against the public interest. It's going to put our trade in GMO free and organic crops at risk.[180]

Labour argued that the GMAC's secrecy over the existence of the trials and the alleged secrecy in respect of breaches during the trials, had resulted in 'the integrity of GMAC … [being] called into question'. [181] They further condemned the GMAC's reluctance to release public reports on Aventis' breaches as '[giving] no confidence to our community'.[182] The Senate Community Affairs Reference Committee [see 3.7] agreed, although perhaps in a more reserved appraisal of the situation, stating:

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[176]Griffin A, '*Gene Technology Bill* 2000 Cognate Bill: Gene Technology (Licence Charges) Bill 2000 Gene Technology (Consequential Amendments) Bill 2000', *House Hansard*, 28/8/2000,p 19449.

[177] *ibid.*

[178] *ibid.*

[179] Stott-Despoja N, 'Genetically Modified Crops: Tasmanian Legislation, Question without Notice', *Senate Hansard*, 9/5/2000, p 14179.

[180] Highfield J, 'Genetic Modified Crops Kept A Secret', *The World Today*, ABC News Online, 27/3/2000, transcript at : <http://www.abc.net.au/worldtoday/s113782.htm> (12/12/02).

[181]Griffin A, '*Gene Technology Bill* 2000 Cognate Bill: Gene Technology (Licence Charges) Bill 2000 Gene Technology (Consequential Amendments) Bill 2000', *House Hansard*, 28/8/2000, p 19449.

[182]McLucas S, '*Gene Technology Bill* 2000 Gene Technology (Consequential Amendments) Bill 2000 gene Technology (Licence Charges) Bill 2000', *Senate Hansard*, 8/11/2000, p 19362.

> [t]he Committee believes that if the development of GM crops is to receive consumer support and confidence, the apparent levels of secrecy surrounding their trialing [sic], as evidenced at Mount Gambier, must be overcome. The oft-repeated aim of transparency underpinning the current legislation can only be achieved if such trials are conducted in an open fashion … The Committee considers that the public will only embrace the developing technology if they have understanding and confidence, which can only be accomplished through honesty and information.[183]

The Federal Opposition and minor parties seized upon the Mt Gambier situation as a justification of the need to regulate. The Australian Labour Party argued that:

> as a result of those issues [at Mt Gambier], the opposition believes that a requirement for full transparency regarding field trial locations should be made explicit in the bill.[184]

The Democrats were even more vocal:

> [I]t is absolutely scandalous, and no wonder the people of Mount Gambier and a lot of people around Australia, but indeed South Australia, are outraged by the secrecy. The public are sceptical, and with good reason. Agricultural biotechnology companies cannot avoid the GM debate by simply calling crops something else. It is irresponsible and, as it has turned out, pretty bad public relations practice in this day and age to keep the public in the dark.[185]

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[183] Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000, para 6.125.

[184] "[I]t is crucial that scientists and industry take the public with them. The government needs to realise that, for this technology to ultimately be a success, the public needs to have confidence in it. If we do not get it right now, the public will never have confidence in this technology" Gibbs B, 'Gene Technology (Consequential Amendments) Bill 2000 Gene Technology (Licence Charges) Bill 2000: Second Reading', *Senate Hansard*, 7/11/ 2000, p 19304.

[185] Stott-Despoja N, 'Matters Of Public Interest: Genetically Modified Crops', *Senate Hansard*, 5/5/2000, p 13384.

3.13 THE SENATE INQUIRY (JUNE 2000)

In June 2000 the Gene Technology Bill and two ancillary bills, the Gene Technology (Consequential Amendments) Bill 2000 and the Gene Technology (Licence Charges) Bill 2000, were introduced into the House. In preparation for debate in the Senate, the Senate the Senate Select Community Affairs Reference Committee [the Senate Committee] was referred the provisions of the Gene Technology Bill for inquiry and report (28th June 2000). [186] The main terms of reference of the Senate Committee were to investigate whether the measures in the Gene Technology Bill were adequate and achieved the desired object of the proposed regime and secondly whether the proposed regulatory arrangements and public reporting provisions would provide sufficient consumer confidence in the regulation of gene technology.[187]

The Senate Committee consulted broadly, receiving 125 written submissions and receiving a 'substantial amount of written material from witnesses'.[188] The Committee also held consultations in major cities through Australia.[189] The Committee concluded its report in time to provide it to the Senate for debate. These recommendations are dealt with extensively later [see 14.4.3], although it is worth noting that the Committee focused heavily on the community issues presented by gene technology and recommended a series of changes to the proposed legislation that would make it more transparent, open and inclusive.

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[186] Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000, para 1.1

[187] The terms of reference to the inquiry were to examine: whether the proposed regulation would achieve its desired objectives; the sufficiency of the Office of the Gene Technology Regulator to oversee the regime; the role of other organisations, including: the Ministerial Council; Consultative committee; and third parties within the overall structure; Liability and insurance of genetically modified crops; the validity of a State opt out clause; the Mount Gambier event and the process processes followed by the Interim Office of Gene Technology in investigating and reporting on the allegations.

ibid, para 1.2.

[188] *ibid*, para 1.4.

[189] *ibid.*

3.14 NATIONAL BIOTECHNOLOGY STRATEGY (JULY 2000)

In July 2000 the Government officially launched the National Biotechnology Strategy. [190] The strategy sets out a framework with which the Government plans 'to capture the benefits of biotechnology development for Australia' in a manner which concurrently ensures the 'safeguarding human health and ensuring environment protection'.[191]

The National Biotechnology Strategy is designed to be a 'living document' that deals adequately with the 'present situation' of gene technology in Australia whilst recognising that the technology is subject to a 'rapidly changing environment'. The key agenda areas of the strategy are:

- Ensuring effective regulation;
- Biotechnology in the community;
- Biotechnology in the economy;
- Australian biotechnology in the global market;
- Resources for biotechnology;
- Maintaining momentum and coordination.

A New System of Regulation. In response to the 'present situation' faced by gene technology (that is, at the time of its promulgation), the National Biotechnology Strategy set down the groundwork for a 'rigorous, efficient and transparent regulatory system' in Australia. The centrepiece of the new regulatory system was to be the creation of a permanent Office of the Gene Technology Regulator (OGTR).

According to the National Biotechnology Strategy, the OGTR would, 'provide a greater level of transparency' than the GMAC system.[192] The OGTR was designed to be the national leader on gene technology issues. However, the OGTR

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[190] Minchin N, *Australian Biotechnology: A National Strategy* Commonwealth of Australia (AGPS) Ministerial Statement 3 July, 2000

[191] Commonwealth Biotechnology Ministerial Council, *National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 1999, p 3.

[192] *ibid.* p 14.

would not be a 'one stop shop' but rather, undertake a 'coordinating function to minimise regulatory duplication' with other Commonwealth agencies that directly or incidentally deal with GMOs.[193] The regulator was to achieve national authority over gene technology through agreement with state and territory governments.

In establishing a national scheme, the Commonwealth resolved to consult with all levels of government and a broad range of stakeholders in order to 'determine how ethical and socio-economic issues can be incorporated in the regulatory process'. The strategy emphasised that regulatory decision making must be based on 'sound scientific risk assessment'. To achieve this aim the Government resolved to develop a framework and methodology for gene technology risk assessment. Furthermore, the regime was to enhance active monitoring of gene technology so as to determine any 'unforseen or unintended consequences' and structure the regulatory regime to counteract those consequences.

Promoting Gene Technology Development. The National Biotechnology Strategy is generally orientated towards the promotion and support of gene technology in Australia. Through it, the government resolves to create an environment in which local industry can compete internationally, through the encouragement of research and industrial links and the better management of intellectual property. The Strategy promises: governmental support to the emerging industry; investment; enterprise development; and funding for education in gene technology. The Strategy also highlights the importance of ensuring that native biological resources are conserved and made accessible to Australians so that local innovation and development is encouraged.

Recognition Of The Need To Involve The Public. The National Biotechnology Strategy also reflects an attitudinal shift by the Government away from a industry specific focus to a more community oriented one [see 14.3]. Community agendas rank second and third after 'ensuring effective regulation' – which is itself designed to assuage community concern and ensure participation and involvement. The community agendas set out by the Strategy are;

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[193] *ibid.* p 14.

- that the community have 'access to quality information' about the 'potential risks and benefits' and 'ethical issues' posed by gene technology and the regulatory system for its oversight; and
- that the community may 'contribute to public policy' relating to gene technology and its regulation.

The Strategy vests Biotechnology Australia with the role of overseeing 'non regulatory' matters. Non regulatory matters, according to the strategy, include the promotion and development of gene technology and the facilitation of 'informed debate and decisions' about the commercialisation of the technology.[194] This reflects a growing awareness that community acceptance and participation is vital to the long-term survival of the industry. The National Biotechnology Strategy asserts that:

> [t]here is a strong preference from the community for the Government to be the primary source of information on gene technology. In order that there is public confidence in biotechnology, it is essential that the community continue to contribute to the development of Government policy.[195]

3.15 MONSANTO'S BREACH (JULY 2000)

Much of the National Biotechnology Strategy was aimed at assuaging community concerns about gene technology by promising effective public involvement in decision making and regulatory reform. It was hoped that this would foster trust between the community, industry and government. The immediate effect of the strategy was however undermined by further high profile mishaps. The first of these occurred literally weeks from its promulgation. In late July 2000 the national press revealed that Monsanto had mixed 69 tonnes of GM cottonseed into

[194] *op cit* 174, p 11.

[195] Commonwealth Biotechnology Ministerial Council, *National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 1999, p 19.

ordinary cattle-feed. The proximity of this event to the Mt Gambier incident [see above], did little to help perceptions of a governmental 'cover-up'.[196]

The mix-up of GM with non-GM seed had been reported to GMAC by Monsanto after an internal audit.[197] However, the Opposition took issue with the fact the breaches were not made public. Rather:

> [t]he public found out that there was a breach, once again through the media, with the report of the breach posted on the web site of the [Interim OGTR] some two weeks after the media report. This is simply not good enough …[198]

The Opposition concluded that:

> once again there has been no openness in the way this technology is being sold to the Australian people and the way it is being regulated and introduced. We need openness. We need a regulator that is there making sure that the industry is regulated and not covering up when a problem arises.[199]

3.16 TASMANIA'S MORATORIUM (JULY 2000)

Tasmania's geographic isolation from mainland has ensured that its agricultural produce has been relatively pest and disease free. Building on this disease free status, as well as the relative lack of pollution and urban development, Tasmania has marketed itself as a 'clean, green' state. The State sees such a reputation as integral to gaining access to niche export markets which pay premiums high quality, organic, or environmentally friendly produce.[200]

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[196]Metherell M, 'Alarm Over GM Seed Mistake', *Sydney Morning Herald*, 25/7/2000, p. 1.

[197] Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000, para 6.119.

[198] Mclucas S, '*Gene Technology Bill* 2000 Gene Technology (Consequential Amendments) Bill 2000 Gene Technology (Licence Charges) Bill 2000', *Senate Hansard*, 8/11/2000, p 19362.

[199] Hall J, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19567.

[200] Hazel B, *Presentation number 33 to the Parliamentary Sub-Committee Investigating the Issue of Genetically Modified*

The global reaction towards gene technology then, was of particular concern to Tasmania, given one of its primary export markets (the niche premiums market) tended to opt for GM/GE free foodstuffs.[201] Moreover, Tasmania's geographic isolation also made it a prime candidate to be a 'GE free' zone helping it to further exploit new niche markets. On the other hand, Tasmania has a large primary sector for which gene technology promised great benefits. The rejection of the technology had the potential to place Tasmania's farmers at a competitive disadvantage against those able to produce higher yielding GM crops. Thus, the State faced a dilemma. It could either refuse the technology and potentially undermine its primary industry's ability to compete against national and international competitors, or accept the technology to the detriment of high premium niche markets, traditionally important to its economy.[202]

The dilemma as to whether to accept or reject gene technology generated substantial public and political debate within Tasmania.[203] The rapid uptake of the technology however, threatened to render the debate futile, as several multinational companies – with the consent of the GMAC – had already begun crop trials within the State. In order to take stock of the situation and provide room for policy development, in July 2000 the Tasmanian Parliament declared all plants modified by gene technology to be pests under the *Plant Quarantine Act 1997* (Tas).[204] The Government justified this action on the grounds that, 'the issues surrounding adoption of GMOs is unclear and with such a degree of uncertainty that the Tasmanian Government is unwilling to have GMOs present in

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Organisms in Tasmania, Quality Assurance Food Safety and Environment Committee, Food Industry Council of Tasmania, Hobart, 2002

[201] Joint Select Committee on Gene Technology (Tas), *Report on Gene Technology*, Parliament of Tasmania, Hobart, 2001, p10.

[202] *ibid.*

[203] Department of Primary Industries, Water and the Environment (TAS) *Gene Technology Position Review Paper*, Department of Primary Industries, Water and the Environment, Tasmanian Government Printing Authority, Tasmania, 2003. pp16-20.

[204] s. 8, *Plant Quarantine Act* 1997(Tas). For background to the inquiry see Joint Select Committee, ibid, pp 7-11.

our agricultural systems until the issues are resolved'.[205] This effectively created a moratorium on all GMOs in Tasmania. It was originally envisioned that such a moratorium would last for at least a year, during which time the Tasmanian Senate Select Committee was charged with inquiring into the implications of adopting the technology.

Tasmanian Field Trials. In order to put the moratorium on GMOs into effect, the Tasmanian Government requested information from the GMAC as to whether any GE crops were being grown in the state. The GMAC informed the Tasmanian Government that, whilst there had been GE activity in the state, this had ceased and that the previous trial sites were now subject to post harvest monitoring. However, it later became clear that this information was incorrect; not only were several trials taking place, but further trials had been planned.[206] Rather than destroying and monitor the post harvest trials (so as to ensure there was no transgenic spread), the GM crops were pollinated to ensure further crop use. The Tasmanian Government alleged that the GMAC was aware of the situation, but failed to release the information.[207] Tasmania claimed it only became aware of the existence of GM crop trials through unofficial channels, more than a year after its moratorium was put in place.[208]

Following the discovery of GM crops within the State, the Tasmanian Government demanded that the Federal Minister for Health and Aged Care (responsible for GMAC) order the immediate cessation of all trials. No immediate response was forthcoming.[209] Only once all pending approvals were granted, did the Federal Minister respond, informing the Tasmanian Government that, as the GMAC was a voluntary scheme, it was impossible to stop the trials. The response caused great consternation within the State, the Tasmanian Government stating:

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[205] Submission No.89, p.1 (Tasmanian Government) to Senate Community Affairs References Committee, A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The *Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000.

[206] Joint Select Committee on Gene Technology (Tas), *Report on Gene Technology*, Parliament of Tasmania, Hobart, 2001, pp 40-41

[207] *ibid.*

[208] *ibid.*

[209] *ibid.*

> [t]his paternalistic and patronising attitude that they know what's best for Tasmania on this issue is abhorrent. They are deliberately keeping this information from the State Government, despite our legal right to have it.[210]

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Not only did this event decrease public trust in the Federal Government but it nearly derailed the implementation of a nationally consistent gene technology regime. Tasmania, which had earlier voiced its reluctance to join a national scheme, now threatened to drop out completely. The result of such action would be to circumscribe the jurisdictional ambit of the proposed regime. The withdrawal then threatened, once again, to scuttle the realization of a national regime, something that had been a key principle from the outset of discussions on the proposed Act.

3.17 TOWARDS REFORM : THE GENE TECHNOLOGY BILL (APRIL-DECEMBER 2000)

The GMAC system was created prior to large scale commercial use of GMOs. At that stage, gene technology was predominantly a scientific endeavour dedicated to research. GMAC then, was designed as a predominantly scientific body, capable of overseeing specialised research oriented work, which had little impact on every day life. However, as gene technology developed into a commercial technology, GMAC's decisions began to hold increasing commercial, legal, ethical, social and political weight. The institutional structure of that body was simply inadequate to deal with these broader issues. This was proven in the series of mishaps and furores which occurred through 2000. Those events proved that neither industry nor a voluntary oversight committee were adequate arbiters of how the technology should be introduced into society, if at all.

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[210] Griffin A, 'Grievance Debate: Gene Technology Regulation', *House Hansard*, 25/6/2001, p 28477.

The Mount Gambier incident and related debacles not only revealed the inability of existing bodies to deal with the commercialisation of gene technology in a manner expected of them by the public; they heavily impacted on the course the new regulation. Those events placed a great deal of pressure on all levels of government to hasten the implementation of a comprehensive national regime. As Corey describes, they 'made discussion of the new Federal Gene Technology Bill more intense than most people expected'[211] and heightened the calls for reform. Such failures placed a greater level of emphasis on matters that were seen as lacking in the current system, such as comprehensive and transparent risk analysis; regulatory independence; public participation and accountability.

Parliament, which predominantly saw the introduction of gene technology as being in the countries long term interest, quickly realised that the failures of the GMAC system should not and could not be repeated.[212] It became evident that the new system had to ensure that the technology was implemented in a manner which accorded with the will of the community.[213] As the Interim OGTR commented:

> given the rapid growth in the use of gene technology, the government's current capacity for intervention is inadequate … The current system … attracts criticism for not being sufficiently open and transparent in its risk assessment and

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[211]Correy S, 'GM crops 2000: The unmaking of a genetically modified PR campaign.' *Background Briefing – Program Transcript (#42/2000),* 26/11/2000, <://abc.net.au/rn/talks/bbing/> (12/11/02).

[212]The Government admitted that, "The recent breaches of canola trial conditions at Mount Gambier highlight the problems of the current system and the need to implement a regulatory system that is independent, open and transparent and which has the authority of accountability and enforcement. The community is right to demand that these mechanisms be put in place as soon as possible to ensure the health and safety of people and the environment while at the same time enabling Australia as a net exporting nation to keep pace with the rest of the world. It is therefore imperative that this stringent Commonwealth legislation be enacted as soon as possible and that this legislation be complemented by similarly consistent legislation by the states and territories." Bailey F, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 21/8/ 2000, p 19548.

[213] "The process must be open, and people must understand what it is that they are committing themselves to, understand the technology and understand the implications of the technology for them. Unfortunately, the government have failed to do this. There has been no scientific rigour placed on the whole process. There have been insufficient trials of genetically modified products. That results in suspicion, and that can result in problems for our society in the future." Hall J**, '***Gene Technology Bill* 2000… Second Reading', House Hansard, 29/8/ 2000, P 19567.

> management processes…. The resulting lack of credibility (particularly in relation to decisions regarding the release of GMOs into the environment) may undermine public confidence and jeopardise the ability of industry to market GMOs and GM products assessed as safe[214]

The Commonwealth introduced a package of legislation comprising of the Gene Technology Bill 2000, Gene Technology (Consequential Amendments) Bill 2000 and Gene Technology (Licence Charges) Bill 2000 in April 2000 for report by September of that year. [215] Attempts to have the time for reporting extended were defeated by the House.[216] The final drafts of the Bills were submitted to the lower house in late June 2000.[217] Debate in the Senate did not begin until the 30th of November 2000, leaving only five days for debate and no time for the Bills to return to the House.[218]

Debate on the Gene Technology Bill is discussed at some length below [see chapters 14-17]. It is also worth noting that both the select committee reports [see 3.7 & 3.13] were used extensively in their respective houses, and influenced the course of discussion and the final wording, scope and provisions of the GTA. These reports, their recommendations and how they affected the debate will also be examined at length later [see 14.4]

The Bill finally became an Act after being passed by both Houses (8th December 2000) and granted royal assent on 21st December 2000.[219] However it did not come into operation until 20 June 2001, with the appointment of a Gene

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[214] Submission No.77, pp.20-21 (IOGTR), to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[215]Submision No.77 (IOGTR), pp 20-21, to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[216] *ibid.*

[217] Minister for Health and Aged Care, *Explanatory Memorandum to the Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000. pp.37-41.

[218] see *Senate Hansard*, 30/11/200, p 20327 onwards.

[219]Submision No.77 (IOGTR), pp 20-21, to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

Technology Regulator (the Regulator) and the establishment of the Office of the Gene Technology Regulator (OGTR).

3.18 CONCLUSION

This chronology shows a move from a disinterested public to an extremely active one. Pre-commercialisation, gene technology was a specialist science, understood and appreciated by few but technical experts. The general community evinced little active interest or understanding of the technology and the legal system reflected this. The GMAC regime, as with its predecessors was overseen and participated in (voluntarily) by specialist, technical experts. The community, indeed the Parliament, had little active input into the operations of this committee or the trials it oversaw.

Post-commercialisation, gene technology quickly became one of the most contentious and debated technologies of recent history. In a few short years from the first modified foodstuff being released on to the marketplace few in society would not have heard of the technology and most would have had an opinion on it. In this environment, the existing system was deemed both impracticable and insufficient to deal with the issues involved. Both the community and the Parliament saw a national regulatory system as necessary to properly counter the risks of technology.

What is important to note at this stage, is that despite the public concern, there has been little actual scientific proof of the 'risks' posed by gene technology. Nor have there been any catastrophes arising from the use of genetically modified food, such as the case of BSE, which, while associated with the backlash to gene technology, arose from a completely different manufacturing process. Whilst there were a series of publicised incidents these were largely managerial and political and had little or no health, safety, or environmental repercussions. Subsequently, the strongest arguments for a regulatory regime to control gene technology were premised on existing management problems. These were,

- the lack of legal backing;
- inadequate risk management;

- too narrow a focus on the repercussions of the science and too little focus on the broader concerns in the community;
- the lack of public input and consultation;
- a lack of transparency; and
- secrecy.

In the next chapter I will discuss the legal response to such concerns, in the form of the GTA. What will become clear over the course of that discussion is that despite the events which drove regulatory reform being primarily managerial and not risk related, the GTA is a strict and comprehensive risk regime. In subsequent chapters I will discuss why – in a climate in which we are ostensibly privatising and deregulating public affairs – it was deemed necessary to create such a substantial and overarching regime and why it became so focussed on 'risk'.

4

GENE TECHNOLOGY ACT

The *Gene Technology Act* 2000 (Cth) (GTA/the Act) is now the primary legislation in Australia regarding the use of genetic technology. The regime is intended to focus specifically on the protection of:

> the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs[1]

This object is to be achieved through a regulatory framework engineered to provide an efficient and effective system for the application of gene technologies.[2] Under this framework a lack of full scientific certainty cannot be used as a basis to forgo cost effective measures to protect the environment.[3]

At the Commonwealth level the GTA acts as a 'gap filler' allowing existing agencies to continue to administer products directly within their jurisdiction.[4] These are the same agencies that GMAC provided advice to (agencies overseeing, foods, therapeutic goods, agricultural and veterinary chemicals, industrial

[1] s.3, GTA

[2] s.4, GTA.

[3] see especially the late addition of s4(aa) which states "where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation"

[4] s.15, GTA.

chemicals; and quarantine [see 3.1.1] . The Act deals with residual and 'gap' products such as living modified organisms (LMOs) and their progeny, laboratory research on genetically modified organisms (GMOs) or animal feed which are currently not adequately dealt with under existing legislation. Products such as therapeutic goods containing GMOs continue to be regulated by the relevant agency with specific expertise in that area of health and safety.[5]

All remaining uses of GMOs – that is conducting experiments with, making, developing, producing, manufacturing, breeding, propagating, using in the course of manufacturing of a thing, growing, raising, culturing or importing GMOs (referred to collectively as dealings) – fall under the jurisdiction of the regime.[6] The Act states GMOs are any organism, 'altered by any technique' that 'modifies the genes or other genetic material' of that organism with the exception of:

a) sexual reproduction; or
b) homologous recombination; or
c) any other technique specified in the regulations.[7]

Importantly sub section c) allows any technology to be declared a genetic technology in the regulations, granting the widest possible ambit to the Act and allowing maximum flexibility to encompass new and novel technologies. All dealings with GMOs without a licence are illegal, unless they are a determined notifiable low risk dealing, exempt dealing or are included on the GMO Register.[8]

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[5] This does not mean that the Office of the Gene Technology Regulator (OGTR), established under the Act will not have a role in the regulation of these products. Under the *Gene Technology (Consequential Amendments) Act* 2000 (Cth) all agencies dealing with products derived from GMOs must consult with the OGTR, take that advice into account and notify the OGTR of the decision.

[6] s.10, GTA.

[7] sub.10(1), GTA.

[8] ss. 32, 33, GTA.

4.1 NATIONALLY CONSISTENT REGIME

The GTA is intended to 'cover the field' so that the Federal Government holds all power to regulate GMOs.[9] Given the lack of any express federal power over areas relating to genetic technologies (such as health, environment or science) the Act provides the Commonwealth power under various broad constitutional grants.[10] These include express federal powers over:

- Constitutional corporations and instrumentalities;[11]
- Commonwealth land;
- things done in constitutional trade or commerce;[12]
- quarantine issues;[13] and

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[9] This is achieved under section 5 of the GTA which declares. It is the intention of the Parliament that this Act form a component of a nationally consistent scheme for the regulation of certain dealings with GMOs by the Commonwealth and the States"

[10] s. 13, GTA.

[11] sub. 51(xx), *Constitution of Australia* 1900. This head of power provides the Commonwealth power to 'regulate the trading activities of a trading corporation'.[*Strickland v Rocla Concrete Pipes Ltd* (1971) 124 CLR 468]. Matters incidental to this power can include any areas which a corporation may enter into in the course of its operation.'[*Commonwealth v Tasmania* (1983) 158 CLR 1]. The growing of GMOs by a company is readily within this definition and therefore any use of GMOs which will eventually be used for sale or profit shall come within the ambit of such a power. In effect this excludes the States from creating a licensing scheme for the use of GMOs by corporations, including their own public corporations and utilities. Bodies trading, supplying researching or developing biotechnology will fall within the Commonwealth law. Furthermore, most farmers are incorporated to limit liability automatically bringing them within the ambit of the scheme.

[12]sub. 51(i), *Constitution of Australia* 1900. This grants the Commonwealth a broad power to regulate on matters regarding inter and intra state trade. Matters incidental to this power include anything related to the preparation or distribution of products for trade.[*O'Sullivan v Noarlunga Meat Ltd (No 1)* (1954) 94 CLR 565.] This power is granted over the "movement of goods … from one State to another, transportation by land, sea or air, and it also includes something such as sales of goods tangible or intangible by persons in on State to persons in another", [*Australian National Airways Pty Ltd v Commonwealth* (1945) 71 CLR 29, 76 per Starke J] The Commonwealth can by virtue of this law exclude the States from specifying transport conditions for products coming from outside the state as well as incidental conditions such as labelling, packaging handling or safety. [S 92 Constitution of Australia 1900 , *R v Wright: Ex parte WWF of Australia* (1955) 93 CLR 127]. Matters relating to the preparation of goods for inter-state or overseas trade will come within the Commonwealth power. For instance hygiene standards and the conditions of premises for the preparation of meat were within the Commonwealths control as that meat was to be exported overseas and those conditions would 'affect beneficially' overseas trade albeit that the slaughterhouse also sold locally [*O'Sullivan v Noarlunga Meat Ltd (No 1)* (1954) 94 CLR 565 at 598.]

- external affairs[14]

These powers provide the Commonwealth the right to control all matters both direct and incidental to the subject matter.[15] The effect of these powers is to, in a very real sense, encompass all but a very few foreseeable dealings with GMOs.[16] Despite the broad ambit of specific and incidental powers, there was some concern that the GTA would not have a complete effect and that gaps could emerge.

The Act makes provisions for State conferral of functions and powers to the Commonwealth, the Regulator or associated bodies under the GTA under the corresponding State legislation.[17] Conversely, the Regulator may delegate power on State instrumentalities to enforce the provisions of the Act or her or his own orders.[18]

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[13] sub. 51(ix) *Constitution of Australia* 1900. Where products or organisms may cause the spread of disease or pests they are automatically brought within the Commonwealth's head of power over quarantine. Given that nearly all new GMOs will likely need to be tested for the potential to spread pests or diseases, they will likely fall within this head of power and thereby the GTA. "Commonwealth control [over quarantine is intended to be] … comprehensive and effective, even if it imposes quarantine laws on *States. A-G (NSW) v Collector of Customs (NSW)* (1908) 5 CLR 818.

[14]sub. 51(xxix), *Constitution of Australia* 1900.

[15] Where any power or control is expressly granted, there is included in the grant, to the full extent of the capacity of the grantor and without special mention, every power and every control the denial of which would render the grant itself ineffective *D'Emden v Pedder* (1904) 1 CLR 92 at 110]. The Federal Constitution grants the Commonwealth Parliament "power to make laws for the peace, order, and good Government of the Commonwealth with respect to … external affairs". Implementation of international treaties automatically extends the ambit of Commonwealth law to the subject matter of the treaty.[s. 109 Constitution; *R v Burgess: ex parte Henry* (1936) 55 CLR 608]. Various treaties are discussed in chapter 12 (text).

[16] Those few dealings that do not involve the potential spread of pests or disease will likely fall within the Commonwealth corporations or trade powers. Furthermore, where a GMO is listed under the Federal requiring notification or licensing, and this listing is based on the environmental, health or safety reasoning the listing will come within this head of power. This means that individuals outside the scope of the corporations power (such as unincorporated farmers) may still be caught within the federal regime by virtue of the quarantine aspects of a required licence.

[17] s.17, GTA.

[18].s.29, GTA.

In order to ensure an effective unified national scheme, the GTA makes provision for an *Intergovernmental Gene Technology Agreement* (2001) (Intergovernmental Agreement).[19] The Intergovernmental Agreement came into effect on the 11th of September 2001.[20] It sets out the obligations of each level of Government with respect to a nationally consistent scheme (mutual implementation, harmonisation of regulatory processes, delegation and performance of functions).[21] The Intergovernmental Agreement also sets out provisions relating to the review of the Act. The Agreement is intended to facilitate cohesiveness and minimise intergovernmental disputes. [22]

Under the GTA, States may enact mirror legislation to give full effect to the regime in each jurisdiction.[23] This corresponding legislation must deal with the GMO as a pest or disease, or it must regulate the use of a GMO by a State Agency or higher education institution.[24] If the Commonwealth permits this declaration the GTA will 'roll back' in these areas and allow the State to operate. Once such a law is in place it can only be amended by a majority of the Ministerial Council under the GTA.[25] To date only Victoria,[26] Queensland[27] and South Australia[28] have enacted such legislation. Outside of the 'roll back' notice provided to the Commonwealth the States retain the incidental power to regulate GMOs indirectly.[29]

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[19] *Gene Technology Agreement*, Between The Commonwealth And The States And Territories, Effective As Of 11 September 2001, the agreement can be found at :
<http://www.health.gov.au/tga/gene/iga010209.pdf> (3/3/03). [herein Intergovernmental Agreement].

[20] *ibid.*

[21] *ibid.*

[22] *ibid.*

[23] ss.12, 14. GTA.

[24] The second grant, provides the States the right to dictate the types of research that may be undertaken upon GMO by state institutions and universities. However, the scope of this grant seems to be narrowed so as to recapture those activities once they move from research to commercial trade.

[25] s.14.GTA.

[26] *Gene Technology Act* 2001 (Vic).

[27] *Gene Technology Act* 2001 (Qld).,

[28] *Gene Technology Act* 2001 (SA).

[29] s. 16 GTA. This means that while the prohibition of a GMO may be outside the State's power it may still fine any person responsible for the release of a GMO through it's environmental, fisheries or land management laws. As stated above, the State may amend existing laws to deal specifically

The provision of most interest to the States was the late addition of s21(aa) to the GTA. The provision allows the Ministerial Council to apply policy principles to those areas designated GM crops and non-GM crops by the States. This is a specific recognition of the rights of the States to create GM-Free zones.

4.2 MINISTERIAL COUNCIL

The GTA makes provision for Ministerial Council, consisting of Ministers from both levels of Government (State and Commonwealth) Governments.[30] The role of the Ministerial Council is to: oversee the operation of the Regulator; issue policy principles and policy guidelines; and to advise the Regulator on codes of practice and standards for persons conducting dealings with GMOs.[31] The role and composition of the council is set out under the Intergovernmental Agreement.[32]

The Intergovernmental Agreement clarifies the role of the Ministerial Council, as set out in the GTA. It also establishes procedures for the appointment, and dismissal of the Regulator and members of each committee. Furthermore, it sets out the obligations of each level of Government with respect to a nationally consistent scheme (mutual implementation, harmonisation of regulatory processes, delegation and performance of functions). The Intergovernmental Agreement also sets out provisions relating to the review of the Act.

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with GMOs but such laws will be excluded from operation if the Ministerial Council decides that they are inconsistent with the national scheme. Furthermore, State's may attempt to pass a general law relating to GMOs with an incorporated clause stating that such legislation was not intended to apply to the extent of any inconsistency with the Commonwealth Gene Technology Act. This would be valid in accordance with s109 of the Constitution and inconsistencies or illegitimate State *enactment*s would be tested on a case by case basis.

[30] sub. 10(1), GTA.

[31] Interim Office of the Gene Technology Regulator, *Discussion Paper: Proposed national regulatory system for genetically modified organisms. How should it work?* , Commonwealth of Australia (AGPS), Canberra, 1999, p. 19.

[32] *Gene Technology Agreement, op cit* 19.

4.3 THE REGULATOR

The Regulator is the primary administrator of the Act.[33] The Regulator is accorded a high degree of autonomy from external influence and maintains the right to independently oversee the regime with minimal constraints from outside bodies.[34]

The Regulator is an individual appointed by the Governor-General with the approval of the majority of jurisdictions.[35] The Governor-General may only appoint the Regulator if it can be shown that the person has no commercial or pecuniary interest in, or was employed in the last two years by, a corporation which produces genetic technologies.[36] The Regulator must further disclose all interests, economic or otherwise, that could 'conflict with the proper performance of the Regulator's functions'.[37] Issues associated with the appointment of the current Regulator will be discussed in detail later [see 9.4.1].

Further to the disclosure requirements the Regulator must report to the Minister annually, or sooner if the Regulator sees fit.[38] The Regulator also has discretion to cause a report about matters relating to his or her functions to be tabled in either House of Parliament at any time.[39]

4.3.1 FUNCTIONS OF THE REGULATOR

The Regulator has a broad mandate which involves her or him in various aspects of genetic technology use and policy in Australia. The primary role is, of course,

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[33] s. 28 GTA.

[34] s.30, GTA.

[35] s.118, GTA. There is no requirement on a jurisdiction to be a signatory of the Gene Technology Agreement to actually contribute to the decision to appoint the Regulator.

[36] subs.118(5),185(6), GTA.

[37] s.120, GTA. Failure to disclose conflicts of interest will result in the dismissal of the Regulator. [sub.119 (b) GTA]. The Regulator may also be dismissed a majority of jurisdictions [sub.119(3)] and the Governor General [s.119(1)], agree that she or he has 'misbehaved'

[38] s.137, GTA. A copy of this report must be provided to each State, [s.126, GTA.]

[39] s.137, GTA.

the determination of applications for dealings with GMOs.[40] Other roles for the Regulator are related to licensing certification and accreditation of bodies involved with GMOs. In pursuance of this determinative role the Regulator participates in the formulation of the policies and principles that underpin the scheme. Concurrently the Act places a substantial obligation upon the Regulator to ensure that information and advice is disseminated to interested parties, including the public and other regulatory agencies that deal with GMO products.[41]

In undertaking her or his role the Regulator is generally obliged to consider issues of health and safety to people or the environment,[42] and may take ethical or community issues into account.[43] The original draft of the Gene Technology Bill required that the Regulator 'have regard to the national interest and to Australia's international obligations'.[44] This requirement was the cause of concern among the public. [45] Following several submissions arguing that it would subjugate the obligation to protect the public to trade related concerns it was dropped from the Bill.[46]

Delegation. The Regulator may delegate any of his or her powers or functions to an employee of the Department of Health or Aged Care, or an employee of another Commonwealth Department, authority or State agency whose functions relate to GMOs and GM products.[47] In order to assist the Regulator in the

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[40]s. 27, GTA.

[41] s. 27(e) GTA.

[42]ss.3,4(aa); 21(3); 38(1)-(2); 47(2)-(3); 49(2); 51(2)(i); 56(1); 56(2)(d); 58(1)(b); 62(2)(g)&(j)&(o); 62(3); 65(1)(a); 66(a); 70(3); 72(6); 74(3)(b); 79(2)(b); 89(6); 97(6) 146(1)-(2), GTA.

[43] ss.107,111, GTA.

[44] Proposed s. 47(1)(c) *Gene Technology Bill*, Consultation Draft (16/12/1999)

[45]Interim Office of the Gene Technology Regulator, *Explanatory Guide to the Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000, p 21.

[46] *ibid.*

[47]s.29 GTA. This enables the Regulator to delegate to a relevant agency such as the NRA or ANZFA. The Commonwealth considers that this will ensure that like products are regulated in a like way. [Commonwealth office of Health and Aged Care, *Gene Technology Act 2000 Supplementary Explanatory Memorandum*, Commonwealth of Australia (AGPS), Canberra, 2000] However given the role of the legislation is to be a gap filler and not to cover the field, no provision is made to ensure that these agencies adopt the Regulator's guidelines. Whether these all agencies harmonise risk and safety management in relation to GMOs will be an issue of policy and not law.

administration of her or his functions the Commonwealth has established the Office of the Gene Technology Regulator (OGTR).[48]

Consultation. In undertaking her or his statutory obligations the Regulator may consult a wide range of bodies, including three advisory committees established under the Act, licence applicants, States, local councils or any body considered appropriate by the Regulator.[49] On the whole it is at the Regulator's discretion to consult these bodies, and where such consultation occurs the Regulator is not bound to apply the advice.[50] This reflects a high level of statutory independence from direct exterior control.[51]

Rather than direct control from exterior bodies the Regulator is bound to act in accordance with codes set out down the Ministerial Council. The majority of these codes are influential, with 'policy principles' being the only binding rule on regulatory decisions[52].

Policy Principles & Guidelines. The Regulator is bound by policy principles that are formulated by the Ministerial Council. Generally policy principles will relate to ethical issues or State designated GM or GM free zones.[53] However the Regulations may extend the scope of policy principles.[54] Where a policy principle has been enacted, the Regulator cannot grant a licence that would conflict with the

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[48] See OGTR website <http://www.ogtr.gov.au/> (5/12/02).

[49] see ss.44,47, GTA.

[50] In all but a few instances it is the Regulators discretion and not an obligation to consult such bodies The exceptions are; risk assessment and management [subs.50(3), 50(3), 56(2) GTA]; revocation of a licence [sub 72(4) GTA]; revocation or suspension of certification [sub.89(4), GTA]; suspension or cancellation of accreditation [sub 97(4) GTA]. Where the Regulator does, or is compelled to, consult other bodies, this advice will be considered or 'taken into account' but is not actually binding upon the decision of the Regulator.

[51] s. 30, GTA, states, "… the Regulator is not subject to direction from anyone in relation to: whether or not a particular application for a GMO licence is issued or refused; or the conditions to which a particular GMO licence is subject."

[52] s.57, GTA.

[53] subs, 21(1)(a)-(aa), GTA.

[54] s. 21(b), GTA.

principle.[55] Decisions of the Regulator may also be influence by 'policy guidelines', which are also established by the Ministerial Council.[56] The guidelines are intended to apply to all 'matters relevant to the functions of the Regulator'.[57] Unlike policy principles these guidelines are not binding upon the Regulator insofar as it can be shown regard was had to them in the licensing of dealing.[58] Furthermore policy principles need only be considered in relation to a licence if they relate to 'risks' or 'ways of managing such risks' so as to protect human health or the environment.[59]

4.4 ADVISORY COMMITTEES

The Act establishes three advisory committees:

- the Gene Technology Technical Advisory Committee (the Technical Committee),
- the Gene Technology Community Consultative Committee (the Community Committee), and
- the Gene Technology Ethics Committee (the Ethics Committee).

The Minister appoints all members of these three committees after consultation with: the States; the Regulator; non-government organisations deemed relevant; and other appropriate Ministers. Members of the committees will hold part time paid appointments. The chair of each committee must be agreed to by a majority of jurisdictions.[60] All three committees provide advice only at the request of the Regulator, or Ministerial Council.[61] None have a mandate to undertake

[55] s. 57(1) GTA. Indeed if the Regulator is satisfied that an application would breach a policy principle she or he needn't even consider the application. [s. 43(e) GTA].

[56] s.23 GTA.

[57] *ibid.*

[58] s.56 GTA.

[59] sub.56(d), GTA. The implication being, that the Regulator needn't consider policy guidelines associated with the ethical, general or community concerns relating to GMOs.

[60] subs.100(8),108(6),111(7), GTA. The Act does not make provision for the disclosure of conflicting interests that committee members may be subject to. This is instead left to the *Gene Technology Regulations* (2001) (Cth) [herein Regulations] [subs 104(1)(c), 110(1)(c) and 115(1)(c), GTA.]

[61] ss.101,107,112, GTA.

independent review or recommendations, although the Regulator is obliged to consult with the Technical Committee in respect of some aspects of the licensing process [see 10.2.3]. Appendix 1 summarises the various roles and responsibilities of each committee.

4.5 TIERED LICENSING SYSTEM.

Like the previous GMAC system the GTA establishes a tiered licensing system that applies differing levels of regulatory scrutiny commensurate to the risks posed by dealing.[62] Under this tiered system all dealings must be licensed unless those dealings are:

- exempt;
- a notifiable low risk dealing ;
- on the Register of GMOs.

The Act does not specifically prohibit any form of dealing with a GMO. Nor is there a register of prohibited dealings listed within the Regulations.

The differing licensing tiers are described below. However, it is important to point out that the operation of the licensing process is heavily grounded in procedural policy and guidelines, which will guide how this tiered (later referred to as a 'bracket-shifting' approach) system works.

The Act establishes a number of codes which influence the decision making process. These are, policy principles, policy guidelines, [see 4.3.1] codes of practice, technical guidelines and procedural guidelines. Given these codes are referred to in several different areas in the Act it is often confusing to glean where and when they apply. Appendix 2 outlines the general application of each.

[62] Office of the Gene Technology Regulator, *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2002, p 1.

4.5.1 EXEMPT DEALINGS

Exempt dealings come within two categories, those exempted by jurisdictional limitation and those expressly declared to be exempt.

The GTA defines a GMO to include:

(a) an organism that has been modified by gene technology;

(b) the progeny of a GMO ; or

(c) things declared by the regulations to be GMOs.

The Act further defines 'gene technology' to include, 'any technique for the modification of genes or other genetic material. So, the legislation bases itself quite centrally around the concept of 'modification'. Any organism that can be shown not to be modified, will fall outside the scope of the legislation unless the Regulator sees fit to place that dealing within the regulations.

'Modify' is not further defined within the Regulations. The term does however have common law meaning, being judicially considered, albeit within different contexts. In environmental law the term has been interpreted to mean being, 'to alter without radical transformation'.[63] Outside of the environmental context the term 'modify' has been taken by the High Court to connote:

> something softer … [to do] no more than to restrain, to make less rigorous or severe, to alter without radical transformation or simply to qualify something so affected. The essence of modification is that its subject remains in being but is altered in some way falling short of extinguishment. All that is needed is that there be partial changes in

[63] *Sydney City Council v Ilenace Pty Ltd* [1984] 3 NSWLR 414 at 421; *North Sydney Council v Michael Standley & Associates Pty Ltd* (1998) 43 NSWLR 468 at 474; "it is correct to say that what there was meant by "modify" was a change which might add to or subtract from the proposed activity, the substance of which continued, and which was less than its wholesale rejection and replacement" [*Transport Action Group Against Motorways Inc v Roads & Traffic Authority & ANOR* [1999] NSWCA 196, at 163.]

> the thing modified. Such changes may enlarge or limit it. The word has a very large denotation.[64]

Under this definition it is questionable whether cloning could be designated modification as it does not actually alter or change the thing modified. Furthermore activities constituting a complete alteration of a parent organism or the creation of a completely new organism may not come within the 'softer' definition that 'modify' has been afforded. For instance, the creation of a unique viral strain which had no relationship to an original strain could very well be an exempt dealing accepting this definition.

The GTA and *Gene Technology Regulations* 2001 (Cth) (the Regulations) specifically exclude certain organisms from the Act.[65] The Regulator maintains the power to add or remove certain dealings from the regulations, subject to policy principles.[66] Among currently exempt organisms are:

- humans for the purposes of somatic cell gene therapy;[67]
- organisms which mutated naturally (without human intervention);[68]
- organisms which are unable to form a viable whole animal;[69]
- organisms formed by: protoplast fusion involving only non-pathogenic bacteria or yeast: embryo rescue: invitro fertilisation: zygote implantation: protoplast fusion between sexually compatible species.[70]

The OGTR, states that the dealings 'must be done within a contained facility and must not involve the intentional release of the GMO into the environment'.[71]

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[64] *Qantas Airways Ltd v Aravco Ltd* (1996) 185 CLR 43 per Kirby J, at 61. Kirby continued to include in the term "Modifications", "additions, omissions and substitutions" This definition has been accepted in subsequent High Court decisions. [*Pyramid Building Society (in liquidation) v Terry & Anor*, HCA, FC 97/040]

[65] sub. 32(3) GTA.

[66] This schedule will be reviewed on a regular basis by the Regulator either by its own volition or through a reasonable request by a member of the public. See Prt.9, Div.7, GTA.

[67] sub.10(d), GTA.

[68] sub. 6(a), Regulations.

[69] sub. 6(c), Regulations.

[70] subs. 6(d)-(e), Regulations.

4.5.2 NOTIFIABLE LOW RISK DEALINGS

Experimental uses of GMOs, that are environmentally contained,[72] fall under the category of 'notifiable low risk dealings' (NLRDs).[73] There are two basic requirements for NLRDs – certified containment facilities and an Institutional Biosafety Committee (IBC). Containment facilities may be certified by the Regulator as to a particular containment level.[74] The specific criterion for each level of containment is set out in the Regulations. In order to gain certification the facility must evince sufficient standards and self-monitoring mechanisms.[75] The certification licence will be granted subject to any conditions the regulator sees fit.[76] In granting the certification the Regulator must have regard to procedural guidelines[77].

An IBC is defined within the Act as a committee established by an organisation accredited under Division 3 Part 7 of the Act.[78] This rather confusing definition is clarified under the *Explanatory Memorandum to the Gene Technology Bill* that describes IBCs as:

> established within Universities, other research institutions and companies. The responsibilities of IBCs include: overseeing work

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[71] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 4. This restriction is not set out in either the GTA or the Regulations;

[72] sub.74(2), GTA.

[73] s.74, GTA. This is a legacy of the GMAC administration. GMAC allowed certain experiments in biologically contained facilities or suitably small scale activities to operate without GMAC assessment as long as those managing the dealing established an internal safety committee to oversee the activity. The Act has retained this scheme in the form of NLRDs, which will be specified under the regulations and will be restricted to a specific class of dealing and class of GMO

[74] s.83, GTA.

[75] s.90, GTA.

[76] ss. 84, 90, GTA.

[77] s. 98, GTA.

[78] s.10, GTA. For someone unfamiliar with the IBC scheme established under the GMAC system this division would not clarify matters. In fact there is no where in the act that clearly spells out what an IBC is, who would operate it, how one would be monitored or indeed its exact role.

> within institutions: providing information and advice about the work to GMAC: and inspecting laboratories.[79]

The rules specifying the constitution of the IBC are set out within the Regulations.[80] The IBC must endorse any information provided to the Regulator, as part of a licence or an NLRD, providing its opinion on the manageability, operability and safety of the dealing. [81] The IBC must keep a constant supervision of the dealing and record all details involved in the dealing.[82] In certifying an IBC the Regulator must have regard whether the IBC can fulfil those obligations and ensure that the IBC members are indemnified.[83] Bodies unable to establish their own IBC they will be required to rely on an established IBC, for instance a University or research institute.[84]

In order to declare a dealing an NLRD an IBC must certify:

- that the dealing is biologically contained;
- would involve minimal risks to human health and the environment, and;
- all risks posed by the dealing can be easily managed.[85]

If the IBC is assured that the dealing is of 'low risk' it can notify the Regulator of the activity, for which the Regulator gives final approval. The Act provides for variety of conditions to be specified in the Regulator's approval of the NLRD.[86]

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[79] Explanatory Guide *op cit 45,* p 45.

[80] s.98, GTA.

[81] The IBC must also review personnel training and supervision as well as the plant's containment facilities. See sched.3, 3.3, scheds.4, 1.6, 2.12, Regulations.

[82] See for instance sched.4, 2.1.7(f), Regulations.

[83] subs. 92(2)(a)-(d), GTA.

[84] No provision is made within the act for a register of IBCs to be kept, which would facilitate finding a suitable IBC for bodies unable to afford or establish their own. Nor are their any provisions for regulating costs which IBCs could potentially charge 'customers'.

[85] *ibid.*

[86] ss.74(4), 75, GTA.

4.5.3 DEALINGS LISTED ON THE GMO REGISTER

The GMO Register (the Register) is a public list of dealings to which unilateral standards apply. That is no case by case assessment is required of these dealings as they have been determined to pose minimal risks.[87] This Register is to contain a list of GMO dealings that are capable of being used commercially without a license.[88] No dealings are currently listed on the register although the OGTR has identified some that may be put there in the future.[89] In order to be satisfied that the GMO should be included on the Register the Regulator must be satisfied that:

- the organism is declared by the regulations to be a Genetically Modified Organism;
- the dealing has been previously licensed;
- the risks can be adequately managed.[90]

The Regulator may specify any conditions under which the GMO can be used. Any person may undertake a dealing listed on the GMO Register without a GMO licence, [91] subject to any conditions specified in the GMO Register. [92]

4.5.4 LICENSED DEALINGS

All other dealings with GMOs, that is, those not included in the GMO Register or exempt and notifiable low risk dealings, must be licensed by the Regulator.[93] Licence applications are required to contain full details of the dealing, including the type of GMO, the type of use, the place in which the use is to occur, the individuals involved in the dealings.[94] A GMO licence may cover the licence-holder and additional persons (such as employees) and will be subject to such

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[87] *ibid*. sub 79(1)(a).

[88] ss. 76-81, GTA.

[89] "There is nothing on the register but we are working on a few things that we think might be put there in the future." *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

[90] ss. 78-79, GTA.

[91] sub. 32(1)(e), GTA.

[92] s.36, GTA, These determinations are disallowable instruments, that is, they are subject to parliamentary review. [sub 78(4), GTA].

[93] sub.32(b), GTA.

[94] s.40, GTA.

conditions as are included in the licence, at the Regulator's discretion.[95] The process of licence approval is discussed below under risk assessment.

4.6 RISK ASSESSMENT

When the dealings to be authorised by licence do not involve intentional release of a GMO into the environment, the Regulator simply prepares a risk assessment and risk management plan.[96] Where the GMO is to be released into the environment and the Regulator determines there is potentially an impact on health or the environment, the Regulator will invite submissions from the public, States, the Technical Committee, the Minister for the Environment and relevant Commonwealth agencies on the granting of that licence.[97]

The Regulator is required to determine whether the dealing is one that may impact on human health or the environment.[98] In considering the licence the Regulator will take into account the:

- degree of risk;
- potential for the spread of the GMO; and
- extent of the proposed dealings.[99]

The Regulator cannot grant a licence if she or he determines that:

- the risks to the environment or to public health cannot be adequately managed;[100]
- the grant would be inconsistent with a Ministerial Policy Principle; [101]or
- the person applying for the licence is not a suitable person by virtue of the Act.[102]

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[95] s.62, GTA.

[96] see Division 3, GTA.

[97] see Division.4, GTA. The Regulator may also consult with 'appropriate' local councils.

[98] s.49, GTA.

[99] s.49(2), GTA.

[100] s. 56, GTA.

[101]sub. 57(1), GTA.

[102]ss.57(2),58, GTA.

If the Regulator determines that these conditions are met then she or he will draft a risk management and assessment plan. In drafting a risk management and risk assessment plan the Regulator must 'take into account' all information collected from relevant bodies.[103] Once the draft plan is complete it is to be made public for comment, submissions and, if the Regulator deems relevant, made available at public hearings.[104]

Upon completion of the consultation process the Regulator will approve the licence, approve the licence conditionally,[105] or refuse the license. The conditions set by the Regulator are discretionary. The stringency of restrictions, type of monitoring and risk minimisation criterion, such as 'buffer zones' will be decided on a case-by-case basis. However where the Regulator wishes to standardise specific dealings she or he may establish 'technical guidelines'.[106]

4.7 MONITORING AND ENFORCEMENT

Self Monitoring. A licensee is under a statutory obligation to inform the Regulator of a breach of permit conditions[107] or any additional information which may impact alter the risks or unintended effects of the use of the GMO granted under the licence.[108] Permit holders who provide false or misleading information or

[103] ss 50-51, GTA.

[104] s.52, GTA.

[105] Particular GMO licence conditions may include requirements that a facility is certified to a particular containment level, or that dealings must be supervised by an Institutional Biosafety Committee established by an accredited organisation. These conditions may include specific provisions about: waste disposal; specified containment levels; specific measures to manage risks; contingency planning; documentation; record-keeping; research; auditing and reporting [subs, 62(2)(l)-(n) GTA] The Act also provides the Regulator with the discretion to require the licensee to insure the dealing against any loss, damage or injury to human health, property or the environment which may arise from the dealing. [s. 62(3), GTA.]

[106] s.27, GTA, These are to be formulated in cooperation with GTTAC and the GTCCG [62(2)(l)].

[107] s.65, GTA.

[108] s.65, GTA. Further conditions regarding self monitoring such as reviews, audits and reporting may be included within the licence.

documents in relation to an application or in required reporting will be held criminally liable.[109]

Inspectors. Inspectors are required to monitor the properties and activities of licensees for potential breaches of the Act.[110] Inspectors are appointed by the Regulator from either the Commonwealth or the States.[111] Generally the inspectors have the power to enter premises to ensure that 'this Act or the regulations have been complied with'.[112] Upon legitimate entry the Inspector may search any part of the premises or anything upon the premises relating to GMOs and take any written or electronic documentation of these things.[113] Inspectors are vested with the right of seizure, [114] search,[115] the right to call on experts[116] and the right to compel the person to undertake appropriate measures.[117] They can also obtain a warrant to monitor, or enter a property against the consent of an owner.[118]

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[109] s.192, GTA.

[110] ss.152,153, GTA.

[111] sub.150(1) No mention is made as to whether an inspector appointed from one State can perform her or his functions in another State, although this would seem to be the case.

[112]ss.151-152. General monitoring powers are provided to allow the Inspector to enter the premises of a licensee at any reasonable time, without their consent [s.160, GTA] The Act extends these powers to allow the Inspector to enter any other property with the owners consent. To legitimise this entry the Inspector needs to inform the individual of their rights to refuse entry (should they not be a licensee) [s.159, GTA] and produce an assigned photo identity card [s.160 GTA].

[113] s.153(1), GTA.

[114]If an inspector finds something on the premises which may breach the Act and has reasonable apprehension that this evidential material will be destroyed or tampered with, they may secure that thing until a warrant is obtained to remove it. [sub, 153(1)(h), GTA.].

[115]s.155, GTA. If the Should the Inspector believe there to be evidential material upon the premises they may search any thing on the premises for evidential material, not simply those things relating to GMOs and or conduct any manner of tests upon those materials.

[116] Where expert opinion is required to establish whether a thing contravenes the Act and inspector can bring an expert upon the property to operate or test that thing.[sub 157(2), GTA. (extended by magistrates order (sub 157(4), GTA.)].

[117] sub.158(2), GTA.

[118]Should the Inspector require an extension to their monitoring or offence related powers, for instance to enter the property of a non licensee without that owners consent, they must obtain a warrant [subs.152(2)(b), 154(2)(a) GTA.] Warrants are to be issued by a Magistrate in relation to either monitoring or offences [s.172 GTA]. Both may be applied for either orally or by affidavit including one by electronic communication means [s.174, GTA]

Inspectors also monitor goods imported and exported from Australia, having jurisdiction to search bags travelling in or out of the country.[119]

Where the Regulator has determined that there has been, or will be, a breach of permit conditions it may give directions for the remediation or avoidance of that offence.[120] Offences against the Act are sanctioned as criminal.[121] Companies are vicariously liable for actions of directors, employees and agents[122] unless the body corporate undertook reasonable precautions and due diligence to avoid the conduct.[123]

If the person does not take the required steps within the time specified, the Regulator has power to arrange for those steps to be taken, and can recover the costs of any such action from the person.[124] The Court may order a forfeiture of any thing allowing the continued breach of the Act.[125] Individuals or corporations may be strictly liable under the lesser provisions of contravening a GMO Register condition or undertaking a notifiable low risk dealing contrary to the conditions set down in the regulations.[126]

4.8 THE RECORD

Under section 138 of the GTA the Regulator (more aptly the OGTR) is obliged to maintain a record of GMO and GMO product dealings. This record includes all

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[119]s.164, GTA. This right extends to searching all contents in bags, requiring the owners of those items to answer questions, and seizing evidential material. [ss.164(2)-(4), GTA]. Refusal to answer questions is a criminal offence [s.165, GTA]

[120]s.146, GTA.

[121] s.146(1)(b), GTA. The extent and types of orders the Regulator may require are not set out in the legislation, which would indicate this power is broad. This power will be able to be enacted regardless of a permit awarded under the Act

[122] sub.188(1), GTA.

[123]subs.188(2)-(3), GTA. By virtue of the Crimes Act the corporation will be liable for five times the fine of an ordinary citizen.[sub.4B(3) *Crimes Act* 1914 (Cth)].

[124] subs.146(4),146(5), GTA. Note however, the Act makes no provision for cumulative sanction where the breach continues after notification of offence.

[125] s. 148, GTA.

[126]ss. 36-37, GTA.

dealings, uses, and derivatives of GMOs, regardless of whether they fall under the auspices of the GTA or not. This includes all licensed dealings and NLRDs under the Act (registered dealings will be on a separately publicly available document). It also includes all food, agricultural and veterinary chemicals, therapeutic goods, and industrial chemicals that contain GMOs must be listed. The exception to this rule is commercially confidential information.

Information contained within the Record relates to the organism, how it has been modified, for what purposes, for what purpose it has been licensed and to whom the licence has been issued. The record is available on the OGTR website,[127] and available through other means by request of the OGTR, ensuring that it is as transparent and as accessible as possible.

4.9 CONCLUSION

The introduction of the GTA remedies a perceived lacuna in regulatory oversight of gene technology. It has built upon previous systems – particularly that of the GMAC – to create a nationally consistent regime, indented to protect public and environmental health and safety whilst simultaneously 'capturing' the benefits of the technology for the 'Australian community, industry and the environment'.

Whilst the system is largely based on the pre-existing GMAC, it is a single Regulator, rather than a committee, who will determine the risks and the measures to attenuate those risks. That Regulator is advised by a much broader range of experts, intended to incorporate ethical and community opinions into the decision making process, as well as the traditional health and safety concerns. The Regulator is to be guided by policies and guidelines set down by Ministers from both levels of Government.

Like GMAC, the GTA operates concurrently with existing regulatory regimes, rather than as a 'one shop stop' oversight body. Unlike GMAC however, it has a much more profound effect on the way GMOs and GM products are regulated.

[127] See <http://www.ogtr.gov.au> (3/3/03).

Moreover, it provides a clear record of how all GMOs and GM products are being used within the country, regardless of which regime they are regulated under.

The GTA is a much stronger, broader and more far reaching regime than the GMAC was or ever could have been. This was very much the intention of the Government, which emphasised that the Act was designed to facilitate a 'rigorous, transparent and accountable decision making process' – one that would ensure 'community input into decisions'. This, the Government stated, would 'go a long way to allaying' the 'substantial community concerns surrounding the introduction of GMOs'. Over the course of this thesis I will examine whether in fact this is the case. In other words: does the GTA achieve its 'desired purpose' of ensuring a rigorous and accountable regime; is it a 'good law' which will encourage community input and support; and indeed 'should it have been enacted' at all?

Whilst the focus of the following analysis is ostensibly the GTA it is my intention to go much deeper and examine the doctrines and theory behind legislative intervention in novel technologies. As lawyers, we often neglect to examine the underlying social and political process of law-making. Generally, our interest in the historical underpinnings of law is limited to constructing the intent of the original lawmakers. I wish to delve deeper into the social, political and legal phenomenon of law making within the context of gene technology. Thus, I will not merely ask whether the law adequately addresses the communities concern with respect to gene technology. Rather, I will consider what was it about the community concern that led to the legal reform? Furthermore, why did the community opt for this form of legal reform? The community is concerned about many things, but not all of them result in such a prominent socio-legal debate or to the creation of new forms of law. This is particularly true in an age of privatisation and deregulation. What unique variables about gene technology made it a candidate for legislative intervention? I believe that by looking beyond the political rhetoric and revealing the deeper basis for legislative reform we can determine whether this law sufficiently placates community concern. Such an understanding might also assist us in predicting the rise of future legislative regimes.

The main reason for legislative reform expressed by proponents of the GTA – and indeed what has become the central premise of the GTA – is that the legislation was necessary to avoid the 'risks' of gene technology. This was, as I outlined in the previous chapter, notwithstanding the lack of any substantiated risks to date and the ongoing debate as to the existence, or severity of such risks. Thus, to comprehend the deeper motivations behind the creation, promulgation and ongoing operation of the GTA I will start at its heart; risk. The following chapter will examine the notion of risk –a central theme in this thesis – its relation to gene technology, and why risks posed by gene technology necessitate legislative intervention.

PART II

RISK GOVERNANCE

5

THE RISK DILEMMA

If there is a unifying theme underpinning the Gene Technology Act (GTA), (apart, of course, from genetic engineering) it is the concept of risk. As noted above, the object of the Act is to:

> protect the health and safety of people, and to protect the environment, by *identifying risks* posed by or as a result of gene technology, and by *managing those risks* through regulating certain dealings with GMOs [emphasis added].[1]

The word 'risk' is used throughout the Act in various forms, described by adjectives such as 'low', 'significant' and 'imminent'. The Gene Technology Regulator (the Regulator) is required by the Act to undertake 'risk assessment' and 'risk management'.[2] Risk language also dominates literature released by the Office of the Gene Technology Regulator (OGTR). The OGTR describes the architecture of the GTA as reflective of a 'risk-based' regulatory system, which establishes 'different levels of approval or authorisation commensurate with the level of risk posed by different types of dealings with GMOs'.[3]

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[1] s. 3, *Gene Technology Act* (Cth) 2000. [herein GTA]

[2] s. 47, GTA.

[3] Office of the Gene Technology Regulator, *Risk Analysis Framework for Licence applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2002, p 1.

The GTA fundamentally revolves around the notion of risk, being both the subject matter of the law (risks 'posed' by gene technology) and the form of the law itself (risk regulation, a risk based approach). It is therefore somewhat surprising – if only to a lawyer – that there is no definition of 'risk' in the GTA. Nor are apparently 'core' methodologies such as 'risk assessment' or 'risk management' included in the definition section of the Act.

Defining Risk. Risk is a common word, used in every day language, to describe a variety of situations or scenarios. For instance, one can refer to 'risk to health', 'risks to the environment', 'economic risks', 'ethical risks', 'legal risks' and so on. Indeed, as will be discussed below, society does not merely 'understand' the concept of risk, it is often *preoccupied* by it. Yet, what will also be examined extensively over the course of the next two chapters is that this social preoccupation with risk has given rise to a complex and technical discipline. This discipline has further spawned a complete lexicon of its own which describes a variety of established scientific, technical and managerial processes.

It is increasingly recognised that risk is not defined solely in technical terms. Risk may also be defined by reference to social or lay language, perception and understanding. What a lay person perceives as 'risky', and how they would go about 'managing' it may often not accord with that of a 'risk expert' and *visa versa*. The problem with such variable definitions is that they may result in definitional gaps between what, on one hand, the public conceives risk to be and on the other hand, what the risk experts do. Subsequently, the original wishes of those in the community who called for legislative intervention, may unwittingly be hijacked to fit into the technical and process specific definition applied by 'risk experts'. This is not to say that the process is flawed, but merely that the community may – when they were informed that 'risks' will be dealt with – conceive of something that is quite different than was actually put in place.

Slovic highlights the effect of this definitional gap, arguing that 'defining risk is an exercise in power'.[4] By this he means that 'whoever controls the definition of

[4] Slovic P, 'Trust, Emotion, Sex, Politics, and Science: Surveying the Risk-Assessment Battlefield, (1999) *Risk Analysis*, 4:**19**: 689-701.

risk controls the rational solution to the problem at hand'.[5] His case is bolstered by regulatory constructs such as the GTA, where the concept of risk not only forms the core basis of the legislation, but also proscribes its jurisdiction. So to ask whether a risk regime 'achieves its desired' purpose requires us to adequately understand what is meant by 'risk' and how the definition adopted affects the way regulatory decisions are made. Hence, over the proceeding chapters I will consider:

- what risk is;
- why it needs to be regulated;
- the development of standard approaches to regulating risk;
- how these processes affect the way we regulate novel technologies such as gene technology; and
- the effect of adopting these processes.

This chapter will focus on the first of these issues. That is, determining what risk is, and particularly what gene technology risk is.

5.1 UNDERSTANDING RISK

The concept of risk is inextricably linked to notions of harm, damage and injury. The Oxford English Dictionary defines risk as, '[t]o hazard, endanger; to expose to the chance of injury or loss'.[6] The terms hazard and risk would then seem interchangeable. However, the UN FAO describes the difference between a 'hazard' and a 'risk' as being that the former describes an agent that may *potentially* cause harm and the latter the *estimated probability* and *severity* of the harm that would ensue from exposure to the hazard.[7] Risk by virtue of this definition is an 'estimation' of the 'probability' of a 'potential' outcome.

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[5] *ibid.*

[6] *The Oxford English Dictionary* Volume VIII, 1970, p 714.

[7] United Nations Food & Agricultural Organisation, *Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System*, FAO Food and Nutrition Division Rome, 1998, Annex 2, p 2.

Perhaps the simplest way to view risk is as a decision making tool. It is the yardstick by which one measures the value in undertaking an activity. Risk is, as Rowe argues, an 'uncertainty principle', the drawback of any gamble or decision that is based on probability of an outcome, which may have positive or negative repercussions.[8] Kaplan and Garrick define risk as ultimately being a mixture of subjective personal values and objective mathematical evaluation.[9] They argue that risk can be described as a relationship between :

- the identification or description of a harmful outcome (the *hazard*);
- the *probability* of that scenario occurring; and
- the *consequence* or evaluation of that scenario. [10]

This evaluation provides a basis from which to weigh up the value in continuing an activity. Yet, as Kaplan and Garrick note, any activity may have multiple outcomes, a plethora of possible damages and varying degrees of harm. No matter how informed a person, none are possessed of the precognitive judgment required to completely identify the outcome of any activity. At best the evaluation process can only be an 'informed guess' about the chance of, and severity of, an outcome – but it is still a guess. The weight given to each of any of the considerations as part of that 'guessing' process may differ substantially between the people evaluating it. Evaluating risk does not simply require one to ask 'will there be an injury?' Rather, it requires an evaluation of the consequence of that injury, that is, 'how badly injured?' This in turn is a subjective question because the degree of 'injury' is intangibly linked to personal factors, perceptions and the economic and or physical situation of the person at risk.

The consequences of losing a dollar may be far more extreme to a pauper than to a millionaire. An consequences of an injury may be far greater to a haemophiliac or to someone with so-called 'eggshell skull' syndrome than the consequences suffered by an ordinary member of the public.[11] Other factors such as paranoia,

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[8] Rowe W.D, 'Understanding Uncertainty,(1994) *Risk Analysis* 5:**14**: 743-750.

[9] Kaplan S, Garrick B.J, 'On the Quantitative Definition of Risk' (1981) *Risk Analysis* 1:**1**:11-27.

[10] *ibid.*

[11] see for instance, Brahams D, 'Clarification Of The "Eggshell Skull" Doctrine' (1995) *The Lancet* 3:**345**:1430; Farrugia A. 'Evolving Perspectives In Product Safety For Haemophilia', (2002) *Haemophilia* 2002 3:**8**:236-43.

phobia or inexplicable physical or mental reactions may also factor into what a person considers in their assessment of an injury. For instance, a phobia of needles can be so overpowering, individuals will forgo proper medical care in order to avoid being injected. The phobia can cause convulsions, respiratory distress or even death.[12] Clearly, where one person may consider the discomfort of an injection to be small and worth suffering, another may consider the injury to be too profound to warrant the 'risk' of not having it.

5.1.1 DEFINING HARM

As defined above, risk describes the probability of 'harm' occurring. This imports further subjectivity into the notion of risk because there is no stable definition for this concept either. Rather harm can have various meanings dependent on the context, the outcome and who is affected.

Harm can be conceived as that which results in personal injury (health, physical safety), mental injury (fear, apprehension, paranoia, phobia) or economic harm (loss of income, loss of property). Yet, harm as a concept may go beyond what is merely physical or pecuniary. In Australia, the broader notion of harm has been recognised under the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* 1999 (National Statement). It states:

> Harm … extends beyond physical harm to a wide range of psychological or emotional distress, discomfort and economic or social disadvantage.[13]

From this perspective, harm doesn't necessarily arise from any direct interference with the body of a person or their chattels. Rather, harm may arise from damaging things which are of social, philosophical or moral value.[14] For instance, the National Statement requires researchers to avoid undertaking activity which might

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[12] Hamilton J, 'Needle Phobia: A Neglected Diagnosis' (1995) *Journal of Family Practice*, 2:**41**:169-175.

[13] See Preamble, National Health & Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans*, NHMRC, Canberra, 1999, p 3. [herein NHMRC National Statement]

[14] Interestingly, 'moral hazard' not only connotes an ethical harm but it has been coopted into economics so that it refers to 'the way insurance affects the behaviour of the insured'. See Steelman A, 'Moral Hazard', (2003) *Region Focus* 1:**7** 10.

harm the 'dignity' of the patient.[15] This includes, *inter alia*, the requirement that researchers protect the 'privacy, confidentiality and cultural sensitivities of participants'[16] by having regard to the 'welfare, rights, beliefs, perceptions, customs and cultural heritage of persons involved in research'.[17]

The GTA itself also accepts a broader context for what is harmful when it speaks of 'risks to the environment'. Although environmental harm may ultimately have an effect on human health or property, the concern to avoid such harm equally derives from more esoteric value judgments about the beauty, integrity and naturalness of the environment.

There are then diffuse social and legal definitions of what is 'harmful'. Given harm is a core element of risk, then risk too may be reflexively constructed to have diffuse social and legal definitions. It is extremely important to understand the broader construct of harm for two reasons. The first is that, because harm and risk are inextricably related – by definition as well as in the public mindset – and harm has no one meaning, risk must necessarily be seen as possessing indistinct boundaries. This is indicated by how the word 'risk' is used in common language, preceded by various adjectives such as 'health', 'monetary', 'legal', 'ethical', 'moral', 'environmental' and so forth.[18] The common use of the term tends to refer to any activity that may lead to any result in an unwelcome outcome (harm) without reference to the form of that outcome. As will be noted later [see 7.3], this is much broader than the concept accepted into the technical risk lexicon.

The second, and equally important point of examining the breadth of the harm construct, is to re-affirm the subjective nature of risk. Because: risk is constructed with reference to harm; and establishing what is 'harmful' can be subjective, then

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[15] NHMRC National Statement *op cit* 13, Guideline 1.2 at 11.

[16] *ibid*,1.18-1.20

[17] *ibid*, Guideline 1.2 at 11.

[18] For instance, searching the terms 'ethical risk', 'moral risk', 'legal risk', 'environmental risk', returned maximum search results (or more than 10 pages) on interdisciplinary search engines. This included: Lexis-Nexis legal search (natural language)[subscription, legal, http://www.lexis.com (10/1/03)]; Google Web search [open access, general internet, http://www.google.com (10/1/03)] and Proquest Journal Search (boolean) [subscription, cross disciplinary academic, http://proquest.umi.com (10/1/03)].

determining what is 'risky' is often a value laden question. One person may consider there to be little or no aesthetic or natural value in the environment. They would perceive little harm from its destruction and hence activities that may have an environmental impact may be considered to be of little risk. What is taboo in one culture may be perfectly acceptable in another. So whether or not someone's 'cultural sensitivities' have been 'harmed' (as per the NHMRC National Statement) really depends on both an individual's cultural background and whether they identify and uphold those cultural values. An activity that puts one person's culture at 'risk' may not even be a consideration to another.

5.1.2 TECHNOLOGY AND PUBLIC RISK

In the previous section I examined the common perceptions of risk, noting that they were multifaceted and subjective. Risk as a concept can be further divided into the spheres of personal and public.[19] A risk can be a gamble taken by an individual, the repercussions of which may only affect that individual. On the other hand, a risk can be a gamble taken by an individual or a group of individuals, the repercussions of which affect a wider group or a community. There is a very fine line between these two spheres of risk and in the modern collective, interwoven society, there is cause to question whether any risk a person takes is genuinely their own.[20] Nevertheless, I will maintain this distinction for the sake of the following discussion because, first, it is relevant to how society views risk and secondly, because such a distinction is doctrinally entrenched into the legal system [a matter which is discussed in Appendix 4].

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[19] Huber P, 'Safety and the Second Best: The Hazards of Public Risk Management in the Courts', (1985) *Colombia Law Review* **85**: 27; Gillette C.P., Krier J.E., 'Risk, Courts, And Agencies'(1990) *University of Pennsylvania Law Review*, **138**:1029.

[20] Although in a collective society it is hard to argue that a risk is ever a gamble which will solely affect one individual. For instance gambling with money may only seem to affect the person who may or may not lose their money, but in reality the loss of that money may affect that persons family members or society who may ultimately have to support the person because of bankruptcy or impoverishment. Smoking has in recent history crossed the divide between personal and public. Once considered a 'personal hazard' to ones health, because of its potential carcinogenic affects to the smoker, it has become clear that 'second hand smoke' can also be carcinogenic to those breathing around the smoker. Hence, laws have been enacted to minimise the risks of non smokers in public areas. For instance see: Part IV. *Public Health Act* 1997 (Tas).

A risk likely to harm a group or population, gives rise the following questions:

- against which particular parties should harm be measured; and
- who should measure it?

The bigger the group affected by an activity, the bigger the dilemma. The problem with public risk is that a decision may be made by one individual, which exposes others to a potential hazard without their acquiescence, or indeed knowledge. Given those placed 'at risk' may have a different notion of risk and harm to the one making the decision, there are likely to be many within the group who, given the option, may have chosen not to pursue the activity in the same manner or indeed at all. Indeed, the dilemma is often compounded because there is rarely a single agent responsible for a 'risky' activity but more often several, all of whose influence may vary. Which of these parties should be the ultimate arbiter of what the risk of any activity is can be particularly political and often contentious. Indeed, there is cause to question whether those responsible for exposing others to harm should have any role in measuring risk, or whether in fact it should be those exposed who are ultimately responsible for deciding what the risk is.

The risk dilemma is exacerbated by the rapid acceleration of modern technology. There are two main reasons for this, which I will outline here and then expand on below. The first is that technology introduces novel methods of manufacture, novel substances and fosters shifts in behavioural norms. These hitherto unexperienced scenarios undermine the risk formula because, without comparative data, it is unclear or impossible to determine the exact degree of risk. The second reason for the exacerbation of the risk dilemma is the further concentration (or at least perceived concentration) of control over public risk, into the hands of human or organisational units.

Novel Technology – Novel Risk. The industrial revolution and the subsequent explosion of technological innovation have undoubtedly brought great social benefits and improved various aspects of living. Gene technology is the most recent of a series of technological milestones which have drastically altered the way humans interact with each other and the environment. Electricity, mass and personal transport, modern medicine and telecommunications have all had direct

and incidental benefits to human life. Yet, the great benefits from these technologies have also been balanced by new and often unpredicted risks. New technologies affect all aspects the risk formula by creating unforseen hazards, probabilities and consequences [see 5.1.1]. The following are case examples.

- *New Hazards.* The industrial revolution brought manufacturing and mass production of a variety of products that are integral to modern urban living. On the other hand, that revolution brought with it new concepts of harm, ranging from environmental pollution to abuses of workers in the new factory assembly lines. Whilst such harms had undoubtedly existed prior to the industrial revolution, it was only with that revolution and the profound effect it had on the social and physical structure of society, that such harms began to be truly considered by the greater society to be risks or hazards.
- *Higher Probabilities*. The numerous benefits of the information revolution have greatly increased the incidence of intellectual property, privacy and morality abuses. The internet has not created any truly new 'harms', *per se*, but the probability of those harms occurring has greatly increased due to the medium facilitating the interchange of information among a much greater population at a much higher speed.[21] We now consider 'information crime' to be a real risk of that technology.
- *Greater Consequences.* Nuclear power was heralded as the solution to energy demands, promising cheap, efficient and clean power. Yet it brought with it the threat of cancer causing radiation and the more insidious threat of nuclear war. Both cancer and war existed prior to that technology. It was however the third component of the risk formula (hazard, probability, consequence [see 5.1]) which has so changed our concept of risk. The sheer horror of nuclear war, and the consequences of a 'nuclear spill', have so pervaded the public psyche that the use of the technology seems to many 'too risky'.

[21] For instance, child pornography, credit card theft etc.

Novel technology compounds the risk dilemma because it is often only in retrospect that the hazard, probability or consequence of technology can be truly ascertained. Without sufficient risk data, the exact nature and extent of any risk will remain unpredictable. Technology makes risk more of a guessing game than ever. As Giddens argues, technology places society on a 'high technological frontier' in which there a 'diversity of possible futures' that no one can adequately predict or truly understand.[22]

5.2 THE RISK SOCIETY

In this section I wish to place the risk dilemma into a social context by discussing how society has reacted both to technology and to risk. In doing so, I will establish that risk and technology are fundamentally about the power to decide people's fate. This will be used as a basis upon which to later move from risk theory into legal theory, and examine the reasons behind the intervention of the law in regulatory regimes such as the GTA. Only by understanding why risk is such a dominant concern in modern society can we understand why and how it should be regulated.

Modern technology has allowed the human race to subjugate and control nature in a way never experienced in history before. With it, humans have targeted some of the greatest risks arising from the natural world, and minimised if not eradicated them altogether.[23] The difference between a highly technological society and a low technology society remains an ever visible aspect of the modern world. The developed world has utilised technology to eradicate much of the famine, disease and infant mortality that plague its low tech developing neighbours.

Those in possession of technology are then capable of dramatically affecting the *status quo* of nature, altering it to a desired end and a desired purpose, namely to

[22] Giddens A, 'Risk & Responsibility' (1999) *Modern Law Review* **62**:3.

[23]See for instance, Andre F.E, 'Vaccinology: Past Achievements, Present Roadblocks and Future Promises.' (2003) *Vaccine* 8:**21**:593-5; Horton R, 'WHO: The casualties and compromises of renewal' (2002) *The Lancet* 9317:**59**:1605-1612; Fenner F, 'The Eradication of Smallpox: Edward Jenner and the First and Only Eradication of a Human Infectious Disease' (2001), *The Quarterly Review of Biology*; 4:**76:**476.

decrease natural risks. Therefore technology has brought humanity, or at least sections of it, to such a stage where it has arguably more effect on nature than nature does on it. This marks, according to Beck, a post-industrial phase, in which society is no longer solely focused on production capacity and wealth accrual, but the avoidance of risk, arising from both nature and ourselves. Beck terms this post-industrial society the 'risk society' (Risikogesellschaft).[24]

5.2.1 RISK, TECHNOLOGY AND FATE

Human control over nature has not stopped disasters, fatalities or risks. Rather, it has transformed the way society views those risks and their causes. The modern risk society increasingly perceives itself as ultimately responsible for 'the end of nature' and the 'end of tradition'.[25] The result, posits Giddens, is 'to essentially live in a world where life is no longer lived as fate'.[26] I would agree with this statement, but only to a degree.

Unlike Giddens I would differentiate between 'fatalism' and 'fate'. Whereas prior societies accepted risks with a degree of fatalism, the risk society sees itself, or more aptly, sees institutional actors within society, either as the progenitor of risk or responsible for it, because 'someone' in society failed to attenuate it. By the 'progenitor of risk' I mean that, famine, disease and infant mortality have been replaced by technological hazards 'modern armaments, chemicals and radiation… contaminants whose effects surface only after decades or generations'[27] as what we most fear. These are all derivative of human activity, novel technologies and the subordination of nature.

Society is so certain of its power to control nature that when 'natural disasters' cause actual harm, blame is levied on institutional actors for omitting to avoid,

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[24] Beck U**,** *Risk Society: Towards a New Modernity*, London, Sage, 1992

[25] Giddens A, *op cit* 22, p 3.

[26] *ibid.*

[27] Kasperson R, Kasperson J, 'Risk Communication: The Social Amplification and Attenuation of Risk', (1996) *The Annals of The American Academy of Political and Social Science*, **545**:95.

warn, plan or manage that risk effectively.[28] Hence, the side effect of normalising control over nature, is to shift blame for disasters, from the 'gods' or 'nature', to society itself. Yet, because those exposed to hazards will often have had little input into the risk decision, their 'fate' still remains out of their immediate control.

Looking at the positive outcomes of technological progress also affirms the continuing existence of 'fate' as a social construct. Consider Giddens' 'end of fate' argument. The end of fate is marked, he argues, by a change in modern lifestyle which permits women to escape their 'domestic milieu' and allows men to escape the traditional need to 'work until they retired and then … fade away'.[29] Yet, is this the eradication of fate? The individuals who have so 'benefited' from this revolution have not truly 'made their own fate'. Rather, the new lifestyle choices available to the modern man and woman are the result of risk decisions, taken by various institutional actors in society, which 'paid off'. Those reaping the benefits of these decisions had little input to the risk decision itself.

Few can say they participated in the development or adoption of the technology that resulted in the escape from their 'domestic milieu'. Few could probably escape the technology anyway, given there are few places left on the planet not affected by it. There may even be some who resent the replacement of the simple, natural, outdoor, low-tech 'serfdom' to the chaotic, hectic and isolating technological serfdom of rush-hours, 'nine to five' jobs, and air conditioned cubicles.

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[28] Consider for instance the recent bushfires which destroyed much of urban Canberra. What once would have been fatalistically accepted as a 'natural disaster' resulted in a large degree of social and political blaming against local agencies for failing to adequately manage and avoid the risk. See Koutsoukis J, 'Canberra Braces For More Fires', *Australian Financial Review*, 21/01/2003, p 6. Certainly the incident is not unique, a rather interesting article on the subject was written in the Sydney Morning Herald in 2001 outlining the automatic criticisms against authorities following each successive bushfire in Australia . see Ed., 'A Burning Desire to Blame Someone', *Sydney Morning Herald*, 29/12/2001, p 19; Blame shifting is not limited to bushfires,. The Newcastle earthquake in 1989 attracted criticism against authorities, architects, builders and engineers, even though earthquakes are an extremely uncommon occurrence in Australia. See Smyth T, 'Nature Not The Only Cause Of Newcastle's Nightmare', *Australian Financial Review*, 11/07/1990, p 63; Waller K, 'Earthquake Victims Face Long Court Battle', *Sydney Morning Herald*,19/7/1990, p.5

[29] Giddens A, *op cit* 22.

As Beck notes, there has been a 'revolution of the lay public's social living conditions without its consent'.[30] What technology has done is to *change our fate*, not eradicate it. We may perceive it as our liberator, but it is still out of the control of majority of us.

5.2.2 THE BLAME SOCIETY

I would argue that society still believes in 'fate', it has just changed the agent, so that one's fate is now perceived to be less in the hands of the supernatural and more in the hands of technocrats. The problem with this is that technology can 'become an enemy of its own promise'[31] so that when something does go wrong, it must be the result of an inappropriate use of technology or a mistaken risk decision. Falkiner summarises the problem:

> [w]e should be experiencing more health, wealth and happiness resulting from our unprecedented technological advances but in many ways we are worse off than twenty years ago. This is not because [the sciences and technologies] have failed us. On the contrary, more than ever before, we have the technology resources and manpower to house, clothe and feed ourselves and to enhance our lives ….
>
> Why then are so many societies living lives of quiet desperation? … [W]e must look to the skills with which we develop and apply our superior technology and more plentiful resources to our needs.[32]

Because technology seems to hold such inordinate promise, the negative aspects of life are easily attributable to a failure, not of technology, but of those in control of it. As such, the 'risk society' can be equally seen as a 'blame society',[33]

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[30] Beck U**,** *Risk Society: Towards a New Modernity*, London, Sage, p 206.

[31] Nicol D, Chalmers D, Gogarty B, 'Regulating Biomedical Advances: Embryonic Stem Cell Research' (2002), *Macquarie Law Journal*, **2**:59.

[32] Falkiner T, *Scientific Legislation*, Aristoc Press, Glen Waverley, 1992, pp 1-2.

[33] This is certainly not a new idea, but one put forward by Mary Douglas, at the same time Beck was developing the notion of 'risk society'. However, Douglas' theory has not received the same see critical

because we can attribute many of both the welcome and unwelcome influences on our life to actual, physical and tangible agents. In this blame society, these technocratic agents become both our champions and our demons.

5.3 RISK, TECHNOLOGY AND CONTROL

Nowhere is the blame society more apparent than with respect to the public reaction to gene technology. Gene technology has created a great deal of fear and apprehension among the general populace because of the perceived harms it may cause. The debate about the technology is particularly relevant to the current discussion because it demonstrates the wider notion of harm, and how the concept of risk overlaps social, scientific, cultural and ethical boundaries.

In chapter 2 I explored some of the reasons that various groups considered gene technology to be harmful. These included concerns about the unknown, moral, ethical and economic hazards posed by the technology as well as physical, personal, environmental and food safety hazards. As can be seen from this example the lay concept of risk is, more often than not, an amalgam of perceived physical and non-physical harms.

What is also revealed by the exploration of the perceived threats posed by gene technology is that many of those potential harms, be they physical or not, centre around, or are exacerbated by, the question of control. This is explicit in the concerns expressed over the potential for unaccountable transnationals corporations to 'control life', through either technological (GURTs/terminator genes) or legal (patents) means [see 2.3]. Similar fears are continually expressed about the control such organisations have over drugs, medicines and therapies. The fear that humans will be able to 'control life' also underpins some religious groups exception to the technology because it represents interference in processes only God should control. It is also evident in the labelling debate, as people feel

attention of that of Beck. See Douglas M, *Risk and Blame: Essays in Cultural Theory*, Routledge, London, 1992. see also Felstiner W, *et al*., 'The Emergence and Transformation of Disputes: Naming, Blaming, Claiming' (1981) Law & Society Review **15**:631; Turner B, Pidgeon N, *Man-Made Disasters*, 2nd ed. Butterworth-Heinemann, Richmond, 1997 p *70.*

they are losing control over the right to choose what they do and do not eat. Environmental concerns have at their core the fear that GM crops will be 'out of control' or that those in charge of them will 'lose control' thus allowing them to escape into the open environment.

There is a peculiar irony in the fact that as society as a whole exercises increasing control of the environment around it, individuals within society feel increasing lack of control of their own fate, their own safety and their own rights. As Baum notes 'not having control when one expects to have it appears to have different psycho-physiological consequences than does not having control when one had no expectations for it'.[34] Because the source of that control comes from *within* society rather than from without, risk becomes politicised. Control over public fate, safety and rights are the *sine qua non* of political and governmental power, especially in a democracy.

Technology, Risk and Democracy. Who controls technology and who controls the risks decisions surrounding it, is then, a democratic issue. With the rise of the blame society there has been an increasing emphasis on who should take control of risk, particularly technological risk, and how they should do it.[35] Technocrats hardly seem the right agents because, while they purvey many benefits, they are simultaneously the main focus of blame. Moreover, for the most part, they are unelected, non governmental agents, who, in a democracy, should not be permitted to have absolute reign over society's fate. The question of who should control such risks and how they should do so will be dealt with in the next chapter.

5.4 CONCLUSION

This chapter concentrated primarily on risk theory. In it, I discussed the concept of risk. Risk was defined as a decision making tool which allows an estimation of the

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[34] Baum A, *et al*., 'Natural Disaster and Technological Catastrophe' (1983) *Environment & Behaviour* **15**: 348.

[35] Douglas M, *Risk & Blame: Essays in Cultural Theory*, Routledge 1992, p 15; Turner B, Pidgeon N, *Man-Made Disasters*, 2nd ed. Butterworth-Heinemann, Richmond, 1997, p 70;

probability of harm to be taken into account when considering the pursuit of a course of action. Both because risk is an estimate rather than a mathematical certainty, and because it is based on the subjective notion of harm, I argued that there was a 'risk dilemma'.

The risk dilemma arises when the impact of the risk goes beyond the person or group undertaking the activity and affects a larger group or the whole of society. In such a case the decision to pursue a course of action is dependent on the determination that the value of success outweighs the potential for harm. However, because each individual has their own perspective about *how* harmful something is, or even *what is* harmful, different individuals affected by the outcome of the risk decision may disagree whether it is a worthy enterprise. There is no completely objective way to determine the exact degree of 'risk' in such circumstances.

The 'risk dilemma' is then a dilemma of uncertainty. It is about uncertainty in knowing what the exact degree of risk is, the exact effect of the risk and all the outcomes of the risk. Above, I further explored the notion of the risks of technology and how that propounded the risk dilemma. Technology, amplifies the uncertainty of risk decisions for two reasons.

First, technology makes risk more of a guessing game than ever [see 5.1.2]. That is, it introduces unpredictable variables into any risk decision and decreases the amount of risk data that can be used to draw conclusions about the hazards, probability and consequences of an action. Because technology constantly restructures and reinvents itself, it will continually present this problem. It is, however, novel technologies, such as gene technology – which completely revolutionise the way humans interact with each-other and the environment – that create the most uncertainty. Indeed, the 'unknown' consequences are perhaps the most predominant criticism of gene technology to date.

Secondly, in my view, the bigger the group affected by an activity the bigger the risk dilemma. Technology has so changed the social canvas of society that few, if any, are immune from its impact. The rise of the risk society has meant that

technological societies expend increasing amounts of time attempting to control risks, from nature and from themselves. The rise of the blame society means that the same societies have begun to attribute responsibility for their fate to human agents. Society is increasingly affected by, and we increasingly perceive ourselves to be affected by, the risk decisions taken by technocrats. Hence, technology causes the risk dilemma to be a society wide dilemma. This is particularly true of gene technology, because it potentially affects many of the basic facets of human life. These are: the food we eat; the medicines we rely upon; the environment around us; and the very structure of life itself. Decisions relating to gene technology will have a profound and long term impact on the way individuals live their lives.

6

RISK REGULATION AND THE GENE TECHNOLOGY ACT

In the previous chapter I examined what risk theorists entitle the risk society, and which I also called the blame society. I termed it the blame society because the public increasingly sees the institutional actors within society as responsible for the positive and negative aspects of their life and their fate. The positive aspect of having someone within society to 'blame' for our fate is that they may be subject to the same social forces as the rest of us. Governmental and legal intervention are perhaps the most predominant social forces with which to take control of technology such as gene technology.

The presumption in a democracy, is that decisions about the fate of society need to be undertaken responsibly, either collectively or in a representative manner. It is perhaps because of this un-stated obligation upon the legislature that most regulation has centred around controlling 'risks', arising from a variety of sources, including health hazards, economic and ethical hazards [see Appendix 4]. Such legislation both utilises technology as a device to control risks, and attempts to control the risks created by technology [see Appendix 5]. The device taken in such legislation is ordinarily to 'regulate' by use of delegated legislation (and as will be examined later, *sub modo* licensing). This is the form of legal process adopted under the *Gene Technology Act* 2000 (Cth) (GTA/the Act). Regulation is the most suitable device to control technology because:

- it allows management and oversight of both benefits and hazards;

- it incorporates the flexibility necessary to deal with rapidly changing and evolving science; technology and knowledge as well as provide for emergencies; and
- it allows a 'lay' parliament to set the broad principles and allow technical experts to apply these principles in practice.

Yet regulation is no panacea, insofar as it solves one aspect of the risk dilemma but compounds another. Whilst it assures intervention, it could potentially derogate from the very purpose behind that intervention, being the real and actual control by Parliament over the use and application of the technology.

The very purpose of regulation is to allow Parliamentary 'outsiders' to involve themselves in the process of law making. The problem with this is that it distances Parliament from the decision making process and diminishes its scrutiny and involvement in controlling the subject matter. By delegating power to others, some of the constitutional protections such as the transparency and accountability of both the legislative process and representative government are avoided. These processes serve to assure the people that the power of law is being wielded in a manner accordant to their will.

Regulation must be undertaken cautiously. Just as it permits technology to be appraised in an objective and responsive manner, we must approach it with equal objectivity and consider whether it has been 'taken too far'. We must also be prepared to be responsive, so that where regulation must necessarily utilise mechanisms which take it 'too far' from Parliament and subsequently the people, other mechanisms are built to counter any democratic deficit created. Hence, the legal challenge posed by the new technologies such as gene technology is to create legal systems that can capacitate innovation, advancement and profit without undermining the traditional protections that the law affords.

Risk in Legal Theory. It is both strange and somewhat disappointing that among those recognised as the 'grand theorists of society'[1], who have truly delved into

[1] Being Ulrich Beck, Anthony Giddens, and Pierre Bourdieu Luderssen; see Lüderssen K, 'Enlightened Criminal Policy or the Struggle Against Evil' (2000) *Buffalo Criminal Law Review* **3**: 691. I would also

the problem of risk, there are few, if any, lawyers or legal theorists. Indeed the famous article on 'risk and responsibility', by Anthony Giddens, published in the influential *Modern Law Review*, was qualified with the statement:

> I am not a lawyer, and my knowledge of legal theory is at best strictly limited. I cannot guarantee that what I have to say will even interest most of my audience, let alone prove instructive … [risk] so far as I know does not figure prominently in legal writing.[2]

The lack of 'prominent legal writing' seems, at least to this author, a major oversight. Leaving the examination and construction of risk to social scientists, anthropologists and economists seems to be solving only half of the risk dilemma. As Wells, Morgan and Quick argue, 'blaming can only lead to claiming if the institutional mechanisms are available'.[3] In other words, we can blame others for the fate which befalls us, but without the law there is no resolution to the problem. Similarly, there is little point discussing the rise of the risk society or the blame society (call it what you will), without also examining if the law solves the dilemma this modernisation causes, and if not, how it should go about solving it.

This is not to say the law does not deal with risk, the point of this thesis is to examine an Act which has risk at its core. The GTA is not an anomaly, rather the law is rife with examples of regulatory schemes intervening in technological, economic, legal and social enterprises to offset 'risks' to the public.[4] Lawyers are definitely dealing with risk and technology, at least in an operative, if not in a theoretical, sense. Nor are leading legal scholars ignorant of the implications of modern technology, and the legal quandary that it causes. The previous two Australian Law Reform Commission Inquiries specifically relate to the social,

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include in this list Mary Douglas, Paul Slovic, Peter Sandman, Baruch Fischhoff, Chauncy Starr, Jeanne & Roger Kasperson , Michel Foucault.

[2] Giddens A, *op cit* 22, p 1.

[3] Wells C, Morgan D, Quick O, 'International Torts: A Comparative Study: Disasters: A Challenge For The Law' (2000) *Washburn Law Journal* 39:508.

[4] Gifford D.J, *Our Legal System*, 2nd Ed. Law Book Co. Sydney, 1983, pp 8-11.

legal and economic impacts of genetic science.[5] So too are leading legal academics and practitioners concerned with the risks caused by technology and how technology should be best used in the modern society.[6]

The legal world is then not ignorant of risk, nor technology. The law is both reflective of, and responsive to, the preoccupation with risk and technology in the blame society. The growing crescendo of social debate in the risk society has meant that lawyers are increasingly looked to for solutions to the risk dilemma. Yet, what I believe Giddens is talking about when he posits that risk 'does not figure predominantly in legal writing', is not the lack of concern with 'risks' or 'technologies' but, as Laster asserts, a lack of emphasis on 'the wider social context' of both risk and 'law making'.[7] By this I mean that lawyers tend to focus on individual components of risk, taking it as a given that it is the law's domain to control risk and deal with its social repercussions.

What the 'grand theorists' have presented is a much broader picture of risk. They view the problems presented by individual technologies as reflective of a society wide problem, one which is reflected in the dilemma of how the people's fate should be decided.

Consequently, I will not accept as axiomatic that it is the law's domain to control risks. What I seek to understand is why the law is the best agent to do this, what justification it has to intervene and what purpose lies behind the laws' intervention. This requires lawyers, like risk theorists, to stand back and objectively examine the 'wider social context' of law. Only by undertaking this task can we truly understand if any individual risk regulation 'is a good law' and 'achieves its desired purpose' as a component of the overarching social problem presented by risk.

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[5] See ALRC Web site <http://www.alrc.gov.au/index.html> (12/2/02). Joint inquiry, with the Australian Health Ethics Committee, into the use of human genetic information; and the upcoming Inquiry into patenting of Human Genetic Information.

[6] Justice Kirby is perhaps the most foremost legal authority in this country who has taken a keen interest in the legal implications of modern technology. For a list of his papers see <http://www.lawfoundation.net.au/resources/kirby/papers/date-index.html> (13/2/02).

[7] Laster K *Law as Culture*, Federation Press, Sydney, 1997, p 74

Hence an analysis of the GTA cannot merely look at the structure of the Act to see if it deals with the specific risks of gene technology. It is necessary to understand the social context of law as much as the social context of risk. This chapter now examines the regulation of risks from novel technologies such as gene technology, as set out in the *Gene Technology Act* 2000 (Cth) (GTA/the Act) It will deal in detail with how the GTA, as a regulatory regime, is designed to deal with the peculiarities of technological risk. It will focus upon:

- how the regulatory framework of the Act is established to allow flexible decision making;
- how risk data is to be obtained to make these decisions;
- how that data is assessed;
- the implications of this process in respect of the risk dilemma.

Just as 'regulation' has become a normative legislative 'category', 'risk regulation' is becoming (some may argue it already *has* become) a standardised sub-category within the regulatory process. Much of the process adopted within the GTA was not designed specifically for gene technology risks but adopts a regulatory 'template' that has been accepted as the most effective way of dealing with risks. Therefore, to discuss the process adopted by the GTA, I will place it in context of the larger 'regulatory template' to understand the stated and un-stated processes, rules and assumptions that have affected both the form of the GTA and the manner in which decisions are made in respect of it.

6.1 FLEXIBLE REGULATION

The concept of 'regulation' connotes a demarcation point between activities. Indeed the concept of regulation is fundamentally premised upon demarcating between acceptable and unacceptable behaviour. For the purposes of the GTA what are acceptable and unacceptable behaviour? At the heart of the Act is the expression by Parliament of the need to 'protect' human safety and the environment by 'managing' any risks posed by gene technology. Regulating GMOs like any other novel technology requires finding a demarcation point that

sufficiently allays perceived risks but which does not impact too heavily on perceived benefits. This is really a balancing game in which the Parliament must decide where the line must be drawn between absolute use of gene technology and no use at all. Hence, the central question faced by Parliament in establishing a new regulatory regime is: when and at what level is intervention warranted?

From an economic perspective the question of where to draw the line between acceptable and unacceptable activity necessitates balancing up the various costs of corporate activity. In the simplest sense, this requires consideration of the relative rights of the regulatee and those affected by the behaviour regulated. Coase[8], sees regulation as fundamentally about 'reciprocity', where the degree of interference with one parties rights must be costed at least relatively proportionately to the degree of impact they may have on the body which is to be protected. The problem is that the costs of corporate activity in a novel technology such as gene technology is completely uncertain, because there is no point of reference for that activity.

A more complex economic measure of the acceptability of regulated behaviour is by evaluating the internal and external costs of production of the regulatee.[9] Internal costs of production are those which the corporation takes into account in its decision to produce. These may include labour, manufacturing or product costs. External costs of production are costs which are directly related to corporate activity but which are not taken into account in a corporations decision to produce. These may include pollution, health costs or damage to property. In choosing the type and level of standards to affect a policy, the decision-maker must ascertain what external costs may come from an activity and to what degree external costs should be shifted into internal production costs.

Placing limits on how GMOs are made, cultivated and released will impact on internal costs of production of the GMO industry as well as limiting the industries potential for revenue. While certainly the industry should bear a high proportion

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[8] Coase, 'The Problem of Social Cost', (1960) *Journal of Law and Economics* **3**:1.

[9] Richardson G, Ogus A.I, Burrows P, *Policing Pollution : A Study Of Regulation And Enforcement*, Clarendon Press, Oxford, 1982, p 6.

of its own direct externalities such as pollution or public health safety, it would be economically unfeasible to shift the entirety of external costs to it. The costs of an industry policing all of its activities all of the time would inhibit production and drive up costs both to the industry and consumers. Moreover, if the industry is to be treated as a single entity, setting high standards which drive a vast proportion of costs internal may cause underserved and unwelcome intrusion on individual agents who have little to do with the activity in question. Cranston argues that regulation which imposes costs on the whole industry is 'unsophisticated' and 'unsatisfactory' because:

> Broad standards prohibit all forms of a particular activity, including what may be desirable, on the assumption that the latter is outweighed by what is objectionable. Not only does the economic analysis often seriously undermine this argument, but the fact that many more law-abiding people than evildoers are thus affected dictates a policy of relatively low maximum penalties which clearly lessens the deterrent effect.[10]

Conversely, where regulation is insufficiently broad, external production costs can potentially be borne by innocent third parties. Indeed, even without actual harm, standards which are perceived to have been set too low will draw political and public disapprobation. So, the decision as to where to set the balance point is not only challenging economically it is challenging politically.

With respect to gene technology the question of when and the degree to which interference is warranted is further confused by the form of activity regulated. Given the range of activities and organisms regulated the type of and degree of externalities is broad. The technology is novel and therefore – it is argued by opponents of gene technology that – many risks posed by it are unforeseen or yet to be realised [see 2.3]. Moreover, the industry is expanding rapidly, undertaking and involving itself in new areas of research and development. So, while there may be a measurable standard of impact upon regulatee by regulatory

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[10] Cranston R, 'Reform Through Legislation: The Dimension of Legislative Technique', in Tomasic R (ed), *Legislation and Society in Australia*, Law Foundation of New South Wales, Sydney pp 88-94.

interference, there can be no simple evaluation of impact upon those the GTA purports to protect.

The Impossibility of 'One Off' Balancing Acts. In such conditions it is extremely hard to make a 'one off' estimate of social efficiency. This causes a regulatory 'fog' in which the success of any law cannot be adequately determined except in retrospect. That is because:

- the outcomes and risks of novel technologies are uncertain;
- knowledge and experience is yet to accumulate;
- differing types of organisms in different situations pose different degrees and type of risks,
- there has been little time to test novel products; and
- many of these products and practices are yet to be invented.

The realisation of Parliamentary intention in an environment of flux requires standards to be constantly readjusted and fine-tuned. Therefore the process of regulation must not only be proactive, in ensuring that the levels of risk are suitably maintained, they must be reactive to new technology and new knowledge. This requires an agent or agency to be able to make rules, where necessary, relating not just to classes of activities but to individual ones too. The GTA utilises two legislative tools to achieve such ends, delegation and licensing. I will examine both of these features, the basis for their adoption and their relationship to the risk dilemma.

6.1.1 DELEGATION

In the broadest sense the Gene Technology Act can be defined as delegated legislation. That is, it delegates power to various bodies to undertake the process of quasi-law-making, implementation and enforcement, whom are ultimately overseen by a sole regulator (the Gene Technology Regulator). This now well accepted legislative form is relatively contemporary and can be seen to have developed as a response to advances in science, particularly where they relate to human health and safety (the below discussion is a summary of the more detailed discussion of the rise of delegated legislation and regulation in Appendix 5).

Delegated legislation is immediately distinguishable from the most archaic system of legislation, codified law.

Code law derives uniquely and absolutely from the parliamentary process, ensuring that the people have a direct and unobstructed line of influence over the standards it sets out [see Appendix 5]. Code law creates a certain, definite regime, in which Parliament makes a clear unequivocal statement as to the 'line of the subject's conduct by visible directions'.[11] As legally and constitutionally attractive as this process is, it is logistically and politically unsuitable in some circumstances.[12] Codification requires: first; a relative moral consensus in society about what is right or wrong (criminal matters); and secondly a relatively stable subject matter (such as taxation or employment). With the advent of the industrial revolution – the root of the blame society – there was a proliferation of technologies that were both transitory in nature and morally ambiguous. That is society held to unanimous opinion towards, being perceived as simultaneously beneficial and negative. Conventional legislative forms provided Parliament with neither the celerity nor flexibility necessary to respond to such technologies, and it became necessary to delegate powers to subordinates so as to permit 'the executive [to] work out the detailed application of general principles embodied in Acts of Parliament'.[13] This marked the birth of the delegated regulatory form.

Delegated legislation is now the primary form of law produced by Parliament and has seen as a more attractive option for three primary reasons.

- It allows for a level of technical detail to be considered which is simply beyond the comprehension, resources and time of a Parliament constituted of lay members;
- It allows legislation to be dynamic and the deal with rapidly changing circumstances,

[11]Attributed to Jeremy Bentham cited in *Byrnes v The Queen* (1999) HCA 38, per Gaudron, Mchugh, Gummow And Callinan JJ. at para 11.

[12] *ibid.*

[13] Dicey A.V, *Introduction to the Study of the Law of the Constitution.* 10th ed. Macmillan, London, 1915/1959 (reprint).

- It allows for emergencies.[14]

Delegated legislation is the obvious choice for the solution of the risk dilemma because it solves the first major element of that dilemma, namely that 'technology makes risk more of a guessing game than ever'. Novel science such as gene technology present an 'uncertain future', which can never be fully determined.[15] If we chose to regulate rather than prohibit technology outright that regulation will be formed in technical, economic and logistic 'fog', in that we can never completely determine its scope or impact.[16] Genetic technologies, however, will continue to force a reassessment of what is acceptable and unacceptable. Our notions and perception of risk will evolve and change with the technology. Consequently, the form of legislation necessary for novel technologies must be elastic and responsive, permitting re-evaluation and refinement in what is an inherently unpredictable environment.

Thus far, no other legislative form has proved as responsive as the delegated, regulatory one. It is simply the most practical in the circumstances. Nevertheless, accepting that such a scheme is the most suitable solution to the risk dilemma does not, as of course, mean it is perfectly suited to it. Because parliamentary power is delegated to bodies – most often unelected – outside of Parliament, the democratic ideal is 'watered down'. This is because: first, it distances the people from the exercise of sovereign power; and second those exercising such power are not bound by the conventional legal and political restrictions that bind the legislature.[17] Yet, the principle which underpins the modern legislative process – in Australia as well as other federal systems – is that the people have the ultimate right to decide their own fate, and that legislature is their agent charged with ensuring their will is recognised [see Appendix 4]. Those constitutional

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[14] Pearce D, *Delegated Legislation in Australia and New Zealand,* Butterworths, Sydney, 1977, p 2.

[15]The House Committee inquiring into the *Gene Technology Bill* argued that, a flexible approach was needed 'to adjust to rapid changes in the fields of plant breeding and gene technology'. Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution – Primary Producer Access to Gene Technology*, Report (June 2000), Commonwealth of Australia (AGPS), Canberra, 2000para 7.24

[16] Daintith T, Legal *Measures And Their Analysis: Law As An Instrument Of Economic Policy: Comparative And Critical Approaches*, Walter de Gruyter, Berlin, 1988, 30.

[17] Craig P, *Administrative Law,* 2nded, Street & Maxwell, London, 1989, p 175.

restrictions upon the legislature are specifically designed to ensure that the exercise of sovereign power is done with the ultimate consent of the people.

That the inevitable delegation of powers from this agent is inevitable was recognised early in the constitutional history of Australia. Yet, what the Courts were even then at pains to point out, we must constantly question whether the delegation has been 'taken too far'[18], so that those exercising power are no longer doing so with that consent.

Delegated legislation is acceptable and indeed a necessary aspect of governance, so long as Parliament retains ultimate control. It is at this point that the courts have advocated caution, and sought to build, in partnership with the Parliament, rules ensuring that Parliament remains the sole body responsible for the exercise of power, and that such power is within the limits prescribed by the Constitutional framework under which the Crown operates.[19] Understanding that these checks and balances are essential to maintaining responsible government I wish to go one step further. By this I mean, that I intend to consider the incidental affects of delegation upon the original doctrine of ultimate popular sovereignty, particularly within the context of risk regulation.

I must reiterate my belief that a flexible, delegated process of regulation is the most effective way to regulate novel sciences like gene technology, and that the risk dilemma naturally leads to this conclusion. However, I believe it is important to consider how that framework may, of its very nature, impact on the original reason (stated or un-stated) regulation was necessitated. That is to ultimately ensure the people were the arbitrators of their own fate and retain the right to establish such principles as, in their opinion, shall most conduce to their own happiness.

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[18] *Roche v Kronheimer* (1921) 29 CLR 329 at 335. see also *Crowe v The Commonwealth* (1935) 54 CLR 69. The Privy Council affirmed the position of Dixon, and the rest of the High Court in the *Boilermakers Case*, stating:"The delegation of regulative power by the legislature to an executive body does not mean that the legislature has abdicated a power constitutionally vested in it. For the executive body is at all times subject to the control of the legislature". (1957) 95 CLR 529 at 527.

[19] Wharam A, 'Judicial Control of Delegated Legislation' (1973) *Modern Law Review* **36:** 611–12

6.1.2 LICENSING

No matter how flexible the regulatory process, there will be some situations in which novel technologies present individual and unique variables for which there has been no consideration or contingency. Similarly there will be occasions in which the exact nature or exact risks posed by a genetic technology are not properly dealt with by the statute or the regulations. Whilst the annexing of ancillary regulations to the statute allows the technical aspects of regulation to be flexibly expanded and applied in practice, even this process is, to a degree, not dynamic enough to deal with the subject matter. Whilst regulations are easier to pass through the legislative process, they are 'costly in terms of [the] technology and manpower'[20] required for their design and maintenance and they still require compulsorily periods for Parliamentary approval. To alter the regulations each and every time new risk data arose would be both costly and severely inhibit the operation of the regulatory agency and the movement of products to market. Moreover, it would after time render the regulations so voluminous they would be impracticable, confusing and inaccessible. Therefore there are times when it is necessary to allow a delegate to set standards with respect of individual activities. This regulatory subset is referred to as *sub modo* licensing [see Appendix 5 (p 553)].

Licensing is a core regulatory device within the GTA [see 6.1-6.3]. Miers and Page describe licensing as a 'powerful tool' because it allows the macro policy set out in statute and regulations to be applied in a highly detailed and technical form.[21] Licensing allows for case by case consideration of individual practices and the micromanagement of corporate behaviour through the setting of specific standards to individual activity. It ensures that the external costs of an each activity undertaken can be weighed up and the degree to which those costs should be shifted internally. The licensing system encourages compliance because, 'its primary threat … [is] the revocation of the licence, [sic] so denying the right to

[20] Miers D, Page A, *Legislation*, Street & Maxwell, London 1999, pp 217.

[21] *ibid* 216-217.

continue the activity at all'.[22] Basically, licensing provides a broad ranging and highly detailed degree of power to be exercised over an activity.

Problems with Licensing. Whilst licensing is attractive, in that it provides for a highly detailed level of scrutiny, it can also be intrusive, focussing a great deal of regulatory scrutiny on a single body. Initially, that is, during the regimes infancy, a 'case by case' evaluation of each and every activity that falls under the GTA may be necessary, but as the regime progresses and some novel technologies become standard practice, such overbearing scrutiny will become less relevant and increasingly unwelcome.

The reluctance to allow a narrow case by case licensing approach became evident during the consultations on the Gene Technology Bill where the proposal to consider dealings on a case by case approach was met with general resistance from both industry and non-industry. Industry groups pointed to the fact that such a requirement would encourage costly and unnecessary duplication. It was argued that predicability should be incorporated into the scheme so that regulatees were able to reasonably envision what standards would be applied to common activities.[23] In this sense overly proactive intervention was perceived as unjustified, uneconomic and unwarranted.

Non-industry sectors also criticised adopting a case by case licensing system. They argued such a process could lead to different standards being applied to similar activities because of the 'social and psychological factors which will inevitably intrude into the processes'.[24] Here, the concern was not so much about over-regulation but the potential for a diminution in the overall standard by virtue of variable individual standards.

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[22] *ibid* . p 217.

[23] Submission No.10, p 3 (Agrifood Awareness Australia), to the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[24] This concept will be discussed later under capture theory [see 9.4 (text)].

6.2 BRACKET SHIFTING

The GTA sets out several legislative categories to which a differing scale of standards apply. For the want of a better term, I will refer to these inter-legislative categories as 'brackets'. This term will avoid confusion with the 'categories of law' or 'categories of regulation', discussed elsewhere.

The bracket system is designed to facilitate 'different types of dealings with GMOs [which] present varying levels of risk, and that different levels of assessment and regulatory oversight are appropriate in relation to each.'[25] This provides the Regulator the ability to shift activities into different brackets dependent on the current level of knowledge of risk associated with that dealing. There are two main categories of standards, **use standards** and **operational standards**.

6.2.1 USE STANDARDS

Use standards usually set maximum permissible levels on activity and are set out in four main brackets. These were described in chapter 2. They are exempt, registered, notifiable low risk and licensed dealings [see 4.5-4.7].

The level of interference in activities in each bracket is intended to be 'commensurate' to the *level of risk* posed by differing classes of dealings.[26] The principle separation lies between contained and released dealings. Release dealings are *prima facie* accepted to be of higher risk than contained ones, meaning that, whilst release dealings attract more flexible and reflexive standards, contained ones are to be dealt with in a 'streamlined' way.[27] However, even within released dealings a degree of normalisation is facilitated. For instance, compliance with 'Codes of Practice', may be required as a condition of a licence

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[25] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra. p 44.

[26] Submission No.77, p.59 (IOGTR), to the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[27] *ibid*, p.69.

thereby allowing for the standardisation of some aspects of release dealings [see 10.4].

6.2.2 OPERATIONAL STANDARDS

Operational standards apply to the institutions (accreditation[28]) and the facilities dealing with GMOs (certification[29]). They are usually minimum thresholds which must be met by regulatees. They allow a minimal intervention by the Regulator in supervision of a facility or its operations.

Because operational standards set minimum thresholds and are therefore preconditions to licensing, the Act allows for the creation of technical or procedural guidelines.[30] These facilitate a one-off decision to set any minimum requirements with relation to containment, institutional resources or related matters which apply unilaterally to all institutions. These base standards must be met prior to the application process thus avoiding duplication and alleviating the burden on the decision-maker(the Regulator). However, the Regulator retains the ability to further specify any conditions she or he chooses.

The streamlining of regulation within the 'low risk' brackets is considered necessary in order to avoid the duplication or re-assessment of practices that are substantially similar and/or have developed considerable risk data profiles. The most 'streamlined' bracket category is the GMO register which was 'developed to address this concern by enabling the [Regulator] to enter GMOs on the Register after a period of licensing and demonstration of the absence of risk'.[31]

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[28] Institutions and companies undertaking research and development in genetic technology must be accredited by the Gene Technology Regulator (the Regulator) to have met requisite standards. These standards may require differing conditions depending on the organisation or the type of dealing[prt.7,div.3, GTA].

[29]Certification of facilities allows standards to be set for facilities used to contain GMOs [s.83, GTA] These standards may be applied independently, be imposed by conditions of a GMO licence [s.62, GTA] or required by regulations for the conduct of notifiable low risk dealings [sub.75(2), GTA]. The certification licence will be granted subject to any conditions the Regulator sees fit [ss.84,90, GTA]

[30] ss.90, 98, GTA.

[31]Interim Office of the Gene Technology Regulator, *Explanatory Guide to the Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000, p 46.

6.3 DETERMINING THE BRACKET: BRACKET SHIFTING

This section examines how the GTA directs the decision making process by which the Regulator decides what level of risk is posed by a gene technology dealing and thereby what regulatory bracket a GMO dealing should be placed. The first of these questions is actually quite complex, because the Act makes little mention of how 'risk' will be determined.

6.3.1 OPEN RELEASE DEALINGS.

Under the Act all dealings which are to be released into the environment must either be licensed or listed upon the register. All registered dealings will have at one time been licensed.[32] Therefore all GMOs released into the environment will have undergone a similar process and for the purposes of the immediate discussion I will consider just the licensed dealings.

The Risk Assessment and Risk Management Plan. The Act requires that before issuing a licence the Regulator 'prepare a *risk assessment* and *risk management* plan [emphasis added]'.[33] The 'risk assessment' must 'take into account the risks posed by the dealings … including any risks to the health and safety of people or risks to the environment'.[34] Outside of this obligation there is no definition of what a 'risk assessment' actually is, how the 'assessment' process should be undertaken, or indeed by whom.[35] Nor is there any mention of how various factors will be 'weighed up', how risk data should be collected, collated, evaluated or measured. There is no set process for the 'assessment' of whether a

[32] sub.78(1)(a), GTA.

[33] sub.47 (1), GTA.

[34] sub.47(2), GTA.

[35] Hain M, Cocklin C, Gibbs D, 'Regulating Biosciences: The Gene Technology Act 2000', (2002) *Environment and Planning Law Journal,* 3:**19:**168. Note that the Act does however set out mandatory considerations under sections 49 and 51. However there is no direction on the assessment process proper. Moreover the considerations are broad for instance, the Regulator must determine 'the effect, or the expected effect, of genetic modification that has occurred, or will occur, on the properties of the organism', but there is no statement of how this is to be measured, or what weight is to be given to these considerations in the overall assessment.

licensed dealing is safe enough to be placed on to the 'register'.[36] Similarly 'risk management' is not defined, and as Hain, Cocklin and Gibbs point out there is no guidance on the 'adequacy of risk management options'.[37]

6.3.2 CONTAINED DEALINGS.

According to the Office of the Gene Technology Regulator (OGTR) all contained dealings must also have been licensed at some stage, although this is not specifically stated in the Act, or regulations.[38] Thus, I will again concentrate on the manner in which the risks of licensed dealings are decided upon.

Contained licensed dealings must – like open release dealings – be subject to a 'risk assessment and a risk management plan'.[39] Again, the Act designates no process under which risks are to be 'assessed' or how risks are to be 'managed'. If the contained, licensed dealing has been assessed over time as being safe, then it may become a Notifiable Low Risk Dealing (NLRD).[40]

Before a dealing can be classified as a NLRD the Regulator must 'consider … whether the dealing … would involve minimal risk to the health and safety of people and the environment'.[41] Again there is no process prescribed which might determine the course of such a 'consideration' . It is worth noting here that the

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[36] Although the OGTR states that, in order for a licensed dealing to be 'registered' for commercial release, the risk must have been assessed over time as being 'sufficiently safe … and that safety does not depend on the oversight by a licence holder'. Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 5.

[37] Hain M, Cocklin C, Gibbs D, 'Regulating Biosciences: The Gene Technology Act 2000', (2002) *Environment and Planning Law Journal*, 3:**19:**172.

[38] The OGTR describes NLRDs as dealings which have been 'assessed over time to pose a low risk provided certain management conditions are met', Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 4.

[39] s.50, GTA.

[40] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 4.

[41] sub.74(3)(b), GTA.

process of considering the risk of an NLRD, is referred to also as a 'risk assessment' by both the OGTR[42] and academics.[43]

6.3.3 RISK ASSESSMENT AND MANAGEMENT SOURCES.

Whilst the Act does not define the meaning of, or process relating to, 'risk assessment' and 'risk management' it does require that the Regulator 'undertake or commission research in relation to risk assessment'.[44] Furthermore the Regulator must 'promote the harmonisation of risk assessments relating to GMOs and GM products' and 'monitor international practice' and maintain links with international organisations' relating to the regulation of GMOs.[45] To this end the OGTR cooperates and communicates with several other agencies nationally and internationally about best practice risk assessment and management.[46]

Evidently the Parliament (or at least the legislative drafters) envisioned regulatory risk assessment and management as being a harmonised and standardised practice. As the following discussion will reveal, the reasons why the terms 'risk assessment' and 'risk management' were most likely not defined in the Act is because:

- they are words of technical import, reflecting a internationally accepted practice;
- there is an obligation to apply the practice set out under international guidelines;

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[42]The OGTR describes NLRDs as dealings which have been 'assessed over time to pose a low risk provided certain management conditions are met', Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 4.

[43] Hain M, Cocklin C, Gibbs D, 'Regulating Biosciences: The Gene Technology Act 2000', (2002) *Environment and Planning Law Journal,* 3:**19:**165., Lawson C, 'Risk Assessment in the Regulaiton of Gene Technology under the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001 (Cth)', (2002) *Environmental and planning Law Journal*, 3:**19**:198.

[44] sub.27(h), GTA.

[45] sub ss. 27(i)-(k)

[46] "There are a number of initiatives within the office to build international harmonisation within the office on the release of GMOs into the environment."*Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

- the guidelines are part of an ongoing process of refinement and harmonisation; and
- because they are being refined and harmonised, legislative prescription would quickly render them redundant.

UNDERSTANDING 'ASSESSMENT' AND 'MANAGEMENT'

By not defining regimented processes for risk assessment and management, legislative drafters ensured that the Act did not become a rigid system, incapable of the requisite flexibility to capacitate novel technology. This has permitted the OGTR to set broad guidelines, intended to reflect current 'best practice' for risk assessment and management [see 7.2.2]. These guidelines can be updated, and the approach taken to assessing and managing risk can be determined in the light of new technology and new knowledge. I have explained the importance of such a framework previously. However, I also alluded to the fact that too much flexibility may have equally negative consequences, at least with respect to the risk dilemma. The question that will be considered at length below is whether not defining the process of risk assessment or risk management takes that flexibility too far.

6.4 CONCLUSION

There are few fixed standards set out within the GTA. Instead, activities may be shifted into overall categories to which varying standards apply. This 'bracket shifting' system solves two of the fundamental regulatory problems created by gene technology. First, it provides a flexible system able capacitate the fluidity of gene technology. Second, by categorising classes of dealings into risk brackets and then applying standards within those brackets, the regime is able to narrow the externalities to groups or individual industry members rather than across the whole industry.

The primary shortcoming of such a system is that, the more streamlined the process, the less scrutiny is placed on individual activities. Whilst attractive from an economic perspective, it is arguable that streamlining renders the regime

insufficiently precautionary. By only providing brackets to regulate activities, the Parliament takes a relatively hands off approach to standard setting leaving the decision maker (the Regulator or to a lesser extent the Ministerial Council) to set a balance that they ultimately believe to be correct. Yet, risk is a subjective measure, as is the assessment of the exact benefit of an untested technology. By leaving the decision as to where the balance between risk and benefit lies to a single agency or a single Regulator, Parliament effectively distances itself from politically sensitive decisions. By not defining the process by which the decision is ultimately arrived at the Parliament is even further distanced from those decisions.

More Scrutiny. The second shortcoming will seem somewhat paradoxical and can only be completely justified over the course of the following discussion. It is that, the *greater the scrutiny* on individual activities and thus the greater the power exercised over the technology, the less direct control Parliament exercises over it. This is because the more streamlined activities such as 'exempt' and 'notifiable low risk' dealings will be specified in the Gene Technology Regulations and the alteration of those Regulations must be approved by Parliament. Licensed dealings however, escape this process. Moreover, because they are based on the process of risk assessment and risk management they increase the number of 'outsiders' between Parliament and the final decision.

The Control Paradox. The justification for Parliament giving the Regulator a high level of autonomy over licensing decisions was discussed previously [see 6.1]. That was because of the recognition that there is a certain degree of impossibility in expecting Parliament to approve each licence under the regime. Another justification – that will be examined in chapter 11 – is the perceived need to maintain regulatory independence from both stakeholders and government. This leads to what I refer to as a 'control paradox'. The control paradox arises where the increasing detailed and involved the regulatory process (and therefore the more control over its subject matter), the less direct control Parliament has. This control paradox will be expanded upon through the course of the following chapters.

7

RISK ANALYSIS AND THE GENE TECHNOLOGY ACT

The *Gene Technology Act* 2000 (GTA/the Act) (Cth) is designed to ensure a mixture of regulatory approaches can be adopted with respect to individual or groups of activities. This provides the Gene Technology Regulator (the Regulator) with the option to utilise either an involved and intensive regulation style, or a more 'hands off' and streamlined approach, depending on the nature of the risk posed. The decision as to which style to use is to be determined by the process of 'risk assessment' and 'risk management' – terms and processes that are not defined in the Act [see 6.3.1]. These processes will determine what regulatory bracket an activity will fall under and therefore what level of regulatory intervention is necessary. Therefore those processes will have a profound impact on both industrial activity and the protection of the public. Risk assessment and risk management are then integral aspects of regulating, even though they are not internal to the GTA. Instead, the Act obliges the Regulator to adopt risk assessment and management techniques in accordance with international and domestic practice and to ensure that these processes are 'harmonised' with other regimes [see 6.3.3]. Therefore, just as the purpose and scope of the Act needed to be determined by a fuller, more complete understanding of 'risk', the effect of the GTA upon its subject matter can only be determined by stepping outside the confines of the legislation to examine the exact meaning of 'risk assessment' and 'risk management'.

In Chapter 5, I noted that in the risk society, citizens are increasingly focused on the notion of normalising natural risks. At the same time the rise of a blame society attributes new risks (and indeed benefits) to technological development. The rise of these so called 'societies' is a phenomenon found throughout the world, but particularly in developed countries. Because of this social phenomenon, there has been an increase in legislation designed to mitigate the risks of novel technologies throughout the world (for example, environmental/pollution, public health and reproductive technology legislation).[1] Simultaneously there has been an increasing focus on centralised and nationalised use of novel technologies to mitigate conventional risks (for instance disaster warning systems, pest/weed control, toxic clean-up, public health medicine).[2]

The trend towards governmental oversight of novel risk at the domestic level has ensured a correlative growth in international risk law [see 7.1-7.2]. In short this is because:

- countries concerned about the hazards of imported goods wish to know that the same standards have been applied to those goods as they would domestically;
- because the determination of whether something is 'risky' takes time and resources, it is important not to duplicate that evaluation in two different countries (import and export);
- risk equity dictates that people in one geographic region should not be exposed to hazards simply because they do not have the resources or knowledge to identify and attenuate hazards.

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[1] These will be discussed below [see 7.1-7.2] However, for a general discussion of risk laws relating to novel technology see: Warnock M, 'The Regulation of Technology' (1998) *Cambridge Quarterly of Healthcare Ethics*, 2:**7**:173 ; Richardson G, Ogus A.I, Burrows P, *Policing Pollution : A Study Of Regulation And Enforcement*, Clarendon Press, Oxford, 1982, p 6 ; Glowka L, *The Role Of Law In Realising The Potential And Avoiding The Risks Of Modern Biotechnology*, Background Study No.19, Commission On Genetic Resources For Food And Agriculture, Food and Agriculture Organisation, Rome, 2002 ; Law M, 'The Origins of State Pure Food Regulation' (2003) *Journal of Economic History* 4:**63:**1103 ; ; Gifford D.J, Gifford K, *Our Legal System*, The Law Book Company, Sydney, 1983, pp 187-189.

[22] See discussion above on the 'risk society' [see 5.2] For broader reading on the use of technologies for risk minimisation see: Bureau for Crisis Prevention and Recovery, *Reducing Disaster Risk: A Challenge for Development* ; United Nations Development Programme, New York, NY 10017, USA ; Falkiner T, *Scientific Legislation*, Aristoc Press, Glen Waverley, 1992.

This is not to say the process of development has crystallised and the characterisation of risks remains an evolving field.[3] However, several over-reaching principles and processes may be seen to be well accepted in the international community. As I will explain in greater detail later, many of these international processes and principles have reached a 'critical mass' so that they have had a profound and even binding effect on the course of domestic law [see 7.1.2, 7.1.3].

The lack of prescription within the Act as to the nature and form of risk assessment and risk management, combined with the obligation upon the Office of the Gene Technology Regulator (OGTR),to harmonise these processes with international standards [see 6.3.3], means that how risk is dealt with and defined will be influenced by international practice, disciplines and standards. As I noted earlier [see 5.0] this may mean that what the public, indeed even what legislators, conceived to be subject of the law and the form of the law, may be somewhat different to what is put into practice.

The purpose of the following discussion is to place the GTA in context of the international law. This requires understanding why international standardisation has occurred, its affect and assumptions and the influence it has on the way we deal with the risk dilemma domestically.

7.1 TOWARDS A STANDARD APPROACH

The concept of creating a systematic method for the quantification of probable risk was brought to light with early statistical theory such as the work of Laplace in the early nineteenth century.[4] Over the next century critical thought focused on

[3] Scientific Steering Committee to the European Commission, *The Harmonisation Of Risk Assessment Procedures*, First Report Of The Scientific Steering Committee's Working Group On Harmonisation Of Risk Assessment Procedures In The Scientific Committees Advising The European Commission In The Area Of Human And Environmental Health, Brussels, 2000. para 3.3.

[4] Laplace P.S, *Essai Philosophique Sur Les Probabilités*, Dover, New York, 1814/1951(reprint/English translation).

how decisions should be made based on Laplace's theory of probability.[5] In respect of public policy decision making, especially with relation to public health and safety, theories remained largely academic,[6] at least until the 1940s and 1950s when the United Nations Food and Agricultural Organisation (FAO) and World Health Organisation (WHO) were formed.[7] Thee two organisations operated cooperatively to review health standards in member countries. The first FAO/WHO Expert Committee on Nutrition, in 1949 reported:

> Food regulations in different countries are often conflicting and contradictory. Legislation governing preservation, nomenclature and acceptable food standards often varies widely from country to country. New legislation not based on scientific knowledge is often introduced, and little account may be taken of nutritional principles in formulating regulations.[8]

This report created an impetus towards the equalisation of standards between countries. The first of which was the joint FAO/WHO Expert Committee on Food Additives policy on 'acceptable daily intakes' of these novel products.[9] That Committee established guidelines for the detection, evaluation and testing of hazards arising from food additives.[10]

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[5] Ramsey F.P, *Truth And Probability. The Foundation Of Mathematics And Other Logical Essays*. Trubner and Co., London. 1931; Di Finetti B, 'La Prévision, Ses Lois Logiques, Ses Sources Objectives'. (1937) *Annales de l'Institut Henri Poincaré*, **7**:1-68.

[6] That is, instead of setting out systems for the identification of risks governments would usually empower an officer to use their determine the safety of areas or goods based on the appearance of those goods or the discretion of the officer. For instance the first Australian health law, passed in the colony of Victoria, allowed local health boards to order the 'occupier of [a] house or part therof to whitewash cleanse or purify' the house if it 'appear[s] to the local board of health that any house or part thereof is in such a filthy or unwholesome condition'. [s. 26 *Public Health Statute* 1865 (Vic)]

[7] 1945 FAO 1948 WHO

[8] Joint FAO/WHO Expert Committee on Nutrition, *Report of the First Session.* WHO Technical Report Series No. 16, World Health Organisation. Geneva, 1950, p 16.

[9] Poulsen E, 'René Truhaut and the Acceptable Daily Intake: A Personal Note' (1995) *Teratogenisis, Carcinogenesis, and Mutagenesis* 15: 273-275.

[10] Joint FAO/WHO Expert Committee on Food Additives, *Toxicological Evaluation Of Certain Food Additives With A Review Of General Principles And Of Specifications*, WHO Technical Report Series No. 539, World Health Organisation, Geneva 1974 ; Joint FAO/WHO Expert Committee on Food Additives, *An Evaluation Of The Toxicity Of A Number Of Antimicrobials And Antioxidants*, FAO Nutrition Meetings Report Series No. 31, Food & Agriculture Organisation, Rome, 1962; Joint FAO/WHO Expert Committee on

Increasing concern with national risk law over the next decades, particularly in relation to human health and the environment fostered further developments towards harmonised international risk policy.[11] Probably the most important international measure was the embodiment of the Codex Alimentarius Commission (Codex),[12] at the international level. Codex came under the aegis of the Food and Agricultural Organisation (FAO) and World Health Organisation (WHO) in 1963 and was charged with developing minimum international standards for food safety. Over the next decade the impetus to establish a standardised approach to safety issues expanded beyond food issues. Members of GATT began to discuss the benefits of a unified system to deal with other health and safety concerns, such as sanitary[13] and phytosanitary[14] measures.[15] This led to the World Trade Organisation, Sanitary and Phytosanitary and Technical Barriers to Trade agreements [see 7.1.2].

7.1.1 THE US RED BOOK APPROACH.

The United States (US) has been at the forefront of the international move towards the harmonisation of the risk governance. During the 1970s, the US National Academies of Sciences (NAS) and National Research Council (the peak research body of the NAS, referred to as the NAS-NRC) led an effort to create a unified and systematic approach to risk in public policy. This culminated in the seminal report 'Risk Assessment in the Federal Government: Managing the Process' in

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Food Additives, *Procedures for the Testing of Intentional Food Additives to Establish Their Safety for Use*, WHO Technical Report Series No. 144, World Health Organisation, Geneva, 1958 ; Joint FAO/WHO Expert Committee on Food Additives *General Principles Governing the Use of Food Additives.* WHO Technical Report Series No. 129, World Health Organisation, Rome 1957.

[11]This included the establishment of the Codex Alimentarius Commission (1963) the UN Conference on the Human Environment (1972) and the WHO Environmental Health Criteria Programme (1973).

[12] Codex had been an European agency. For the history of Codex see See Leive D.M, *International Regulatory Regimes: Case Studies in Health, Meteorology and Food*, Lexington Books: Lexington, 1976. p 18-32.

[13] Relating to human or animal health.

[14] Relating to plant health.

[15] World Trade Organisation, *Summary Report On The SPS Risk Analysis Workshop*, WTO G/SPS/GEN/209 (00-4634) , World Trade Organisation, Geneva, 2000, pg 2.

1983. The report has come to be better known as the 'Red Book', (imaginatively named for the colour of its cover) which is the name I will adopt from now on.[16]

The Committee noted that despite extensive discussion of risk oversight no standard definitions or processes had been adopted in either the public or private sectors.[17] In response the NAS-NRC sought to establish a set process for the evaluation of risk.

The first stage of the standardisation of risk oversight by government was to set key terms for the common processes which were to be used in each evaluation. According to the report, the most important of these was the separation between two separate stages of risk oversight. The NAS-NRC termed these **'risk assessment'** and **'risk management'**. The first was the process of characterising the potential adverse health effects of exposure to a hazard. The latter was the process of evaluating alternative regulatory actions and selecting among them.[18] The most stringent recommendation of the report was that these processes should be separated and not permitted to impede upon each-other.

The report further concluded that the process of governmental risk oversight be undertaken in a transparent manner which facilitated public participation in the final decision.[19] The mechanisms to achieve such public participation were not discussed in any detail. The requirement that information was presented to the public to encourage democratic decision making was to be later termed '**risk communication**' and was the subject of a further extensive report by the NAS-NRC in 1989.[20] The development of this aspect of the overall paradigm will be the extensive focus of chapter 11.

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[16] National Research Council (US), *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press, Washington D.C., 1983.

[17] *ibid*, p 18.

[18] *ibid.*

[19] *ibid*, p 153.

[20] National Research Council (US), *Improving Risk Communication.* National, Academy Press, Washington, D.C, 1989.

Risk Analysis. The three step approach of risk assessment, risk management and risk communication, as set out in the Red Book, has been given the name 'risk analysis'. Each of these overall stages – but particularly risk assessment – has been further broken down into sub-stages [see 7.2.1-7.2.3]. In order to avoid confusion the three main stages of risk analysis are referred to as 'pillars' by some authors,[21] I will adopt this terminology.

Risk analysis, as envisaged by the NAS-NRC was premised on the notion that assessing risk is the realm of science, the larger question of whether the activity should proceed is a policy decision, and the communication of that policy is an administrative procedure.[22]

7.1.2 THE INTERNATIONAL IMPLEMENTATION OF THE RED BOOK MODEL

The NAS-NRC 'risk analysis' system provided a clearly defined and systematic set of processes which provided efficiency, certainty and predictability to decision making. This proved to be quite attractive to the government in the US and was implemented in almost every regulatory regime that involved some degree of scrutiny of goods or services.

The willingness of nation states to adopt the trifurcated red book risk analysis paradigm arises partly out of the ongoing process of cooperation in, and input to, the establishment of these international standards by these states. More recently however, the paradigm can be seen to have reached a 'critical mass' in terms of international law, having been incorporated in, or annexed to, international treaties. This means that the standardisation of the risk analysis process is now reciprocal (that is between domestic and international bodies), but weighted towards the international law. That is, whilst domestic processes will still influence the course of international standard setting bodies, the processes adopted by these bodies has a much more profound influence on each nation state.

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[21]Garant R, Davies T, *Understanding Risk Analysis,* American Chemical Society Guide, Office of Legislative & Government Affairs (US), Washington, 1998; Davies J.C, *Comparing Environmental Risks: Tools for Setting Government Priorities.* Resources for the Future, Washington DC, 1996, pp 1-8.

[22] Ruckelshaus W.D, 'Science, Risk, and Public Policy' (1982) *Science* **221**:1027-28.

In a drive to create further standardisation with its trade partners the US led proposals under the *General Agreement on Tariffs And Trade* for the implementation of a unified international approach to risk oversight.[23] Basically, this involved encouraging countries to adopt a Red Book type approach to the testing and acceptance of goods and services. Its most binding form was achieved in 1995 with the annexing of the *Sanitary and Phytosanitary Agreement* 1995 (SPS) and *Technical Barriers to Trade Agreement* 1995 (TBT) to the Marrakech Agreement establishing the World Trade Organisation (WTO). Whilst neither agreement mentions outright the NAS model, both require countries accord their national laws with international standards. These international standards tend to generally reflect the risk analysis process set out by the NAS-NRC.[24]

Relevant International Standards. Three international standards are deemed relevant for the purposes of the SPS. These are the standards set down by;

- the Codex Alimentarius Commission (Codex) for testing the safety of food, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- the Office International Des Épizooties (International Office of Epizootics) (OIE) for animal health and zoonoses; and
- the Secretariat of the International Plant Protection Convention (IPPC) for plant health, and the protection against introduced species.[25]

The TBT Agreement refers to international standards developed by any 'body or system whose membership is open to the relevant bodies of at least all

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[23] World Trade Organisation, *Summary Report On The SPS Risk Analysis Workshop*, WTO Report (G/SPS/GEN/209 (00-4634)) , World Trade Organisation, Geneva, 2000, pp 2-3.

[24] Art.3.1 of the *Agreement On The Application Of Sanitary And Phytosanitary Measures* (World Trade Organisation) 1995 [herein SPS] requires that all member countries 'sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risk to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organisations. Article 2.6 *Agreement On Technical Barriers To Trade* (World Trade Organisation) 1995 [herein TBT] also requires member countries technical regulations adhere to 'appropriate international standardizing bodies of international standards for products for which they have either adopted, or expect to adopt, technical regulations'.

[25] Art.3.1, Annex A.3, SPS.

Members'[26] although the above bodies are generally accepted as the most relevant.[27]

The guidelines adopted by these organisations utilises the Red Book Paradigm and all separate out risk assessment, risk management and risk communication.[28] By falling under the WTO, the Red Book approach can now be said to have 'teeth' because it remains the only international agreement which allows for the implementation of trade sanctions where a country is deemed to be in breach. This means that, to justify any protective measures placed on products, goods or services, (packaging and handling, quarantine, quality control etc) countries must justify that the basis for such measures accords to a process accepted under the WTO Treaty System.

Other Gene Technology Specific Guidelines. Several other guidelines have been established by international agencies (WHO, FAO, United Nations Environment Programme(UNEP), United Nations Industrial Development Organisation(UNIDO)), with specific reference to gene technology. These include the: UNEP Biosafety Guidelines; UNIDO Voluntary Code of Conduct; and FAO preliminary Draft International Code of Conduct on Plant Biotechnology.[29] Whilst these guidelines could, potentially be accepted as relevant to a TBT dispute, they have not, as of yet, reached the status of those set out by Codex, OIE

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[26] Art. 2.4 & Annex 1, para. 4,TBT.

[27]Dawson R.J, 'The Role Of The Codex Alimentarius Commission In Setting Food Standards And The SPS Agreement Implementation', (1995) *Food Control*, 5:**6**:261-265; Swinbank A, 'The Role Of The WTO And The International Agencies In SPS Standard Setting', (1999) *Agribusiness*, **15**:323 ; Newsome R, 'Issues In International Trade: Looking To The Codex Alimentarius Commission', (1999) *Food Technology*, 6:**53**:26.

[28] The International Office of Epizootics extends the process by making hazard identification an initial quasi-step, however for all intents and purposes the system is the same as the Red Book model. [see Arts 1.3.1.1. -1.3.2.2. *International Animal Health Code*, 10th ed, International Office of Epizootics, Paris, 2001; [herein International Animal Health Code]Arts 1.4.1.1. -1.4.1.1.2 *International Aquatic Animal Health Code*, International Office of Epizootics Paris, 2001[herein International Aquatic Animal Health Code]; ISPM. No 2 *International Standards for Phytosanitary Measures Risk Assessment & Risk Management* & *International Standards For Phytosanitary Measures Guidelines For Pest Risk Analysis*, Secretariat of the International Plant Protection Convention, Food & Agriculture Assosciation, Rome, 1996 *;* ISPM 17 *Pest reporting* Secretariat of the International Plant Protection Convention, Food & Agriculture Assosciation, Rome, 2002.]

[29] For a discussion of all these agreements see generally, Glowka L, *The Role Of Law In Realising The Potential And Avoiding The Risks Of Modern Biotechnology*, Background Study No.19, Commission On Genetic Resources For Food And Agriculture, Food and Agriculture Organisation, Rome, 2002.

or the IPPC. Most are in draft or preliminary stages and/or specifically declare themselves to be non-binding. As this discussion is not orientated to an in depth examination of risk assessment or management I will avoid concentrating on these guidelines them at this stage, except to note that all set out the Red Book trifurcated risk analysis process.[30]

Biosafety Protocol. The Red Book model is also accepted by other international agreements, the most relevant of which is the *Cartagena Protocol on Biosafety* 1999 (the Biosafety Protocol). The Biosafety Protocol agreement was annexed to the *Convention on Biological Diversity* 1992 (CBD) in 1999 in order to address the biosafety of Genetically Modified Organisms. The Biosafety Protocol, like its WTO cousins, strives to ensure international consistency in the oversight of risk. It requires that risk assessment be carried out in accordance with scientifically established risk assessment methods and measures are adopted to manage the risks identified by the risk assessment procedure.[31] Parties to the Biosafety Protocol must establish strategies and measures to manage any risks that have been identified in the assessment process.[32] Public awareness and participation are seen as vital to the overall process of risk analysis.[33]

Thus, the three stage risk analysis paradigm is also dominant within this agreement. However the process envisioned by the Biosafety Protocol is not as strictly separated as that set under the WTO regime, and is less emphatic about the separation between science and other considerations in the making of decisions.[34] Unlike the WTO dispute mechanism the CBD does not allow trade sanctions as a remedy. Australia is not a signatory to the Biosafety Protocol, and has expressed

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[30] *ibid.*

[31] arts. 15, 16 *Protocol on Biosafety to the Convention on Biodiversity* (United Nations Environment Programme) 2000 *)* [herein *Biosafety Protocol*] .

[32] arts.8,9, *Biosafety Protocol.*

[33] art.23, *Biosafety Protocol.*

[34]See generally, Safrin S, 'Treaties In Collision? The Biosafety Protocol And The World Trade Organisation Agreements', (2002) *American Journal of International Law* **606**:96; Shaffer G 'WTO Blue-Green Blues: The Impact Of U.S. Domestic Politics On Trade-Labor, Trade-Environment Linkages For The WTO's Future' (2002) *Fordham International Law Journal* **24**:608.

its opposition to entering into it at present.[35] Thus, while this agreement tempers the strictness of the risk analysis process somewhat, it is less influential than the process set out under the WTO regime.

7.1.3 THE ADOPTION OF THE APPROACH TO DOMESTIC LAW.

It cannot be said that there is any definitive international system for overseeing risk. However, the overall 'risk analysis' process set out in the Red Book has been widely accepted by nation states, and universally accepted among Australia's major trading partners, as the proper basis of any competent risk framework.[36] How each stage is applied and the nomenclature given to the individual stages does sometimes differ. However, the basic structure remains the same.[37] That structure separates out risk assessment from risk management and risk communication. It further breaks risk assessment down into specific sub stages [see 7.2.1].

The three stage process was utilised for the first time in Australia in 1986 as part of the national public health policy has underpinned policies[38] and laws[39], relating

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[35] Department of Foreign Affairs & Trade *Cartegena Protocol: Australia's Position*, Department of Foreign Affairs & Trade, Canberra, 2000.

[36]Glynn S, Flanagan K, Keenan M, *Science And Governance: Describing And Typifying The Scientific Advice Structure In The Policy Making Process – A Multi-National Study*, Report (EUR 19830 EN), European Commission, Brussels, 2001.

[37] *ibid.*

[38]For instance, National Health and Medical Research Council *Report Of The One Hundred And Third Session.*, National Health and Medical Research Council, Canberra, 1987. Australian Environment Council, *Guide to Environmental Legislation and Administrative Arrangements in Australia*, Report No. 18, Commonwealth of Australia (AGPS), Canberra, 1986; Australian and New Zealand Environment and Conservation Council, *Australian and New Zealand Guidelines for the Assessment and Management of Contaminated Sites*. National Health & Medical Research Council, Canberra, 1992; Commonwealth Department of Community Services and Health. *Better Health Outcomes for Australians*, Commonwealth of Australia, Canberra: AGPS, 1994; Australian and New Zealand Environment and Conservation Council, *The Assessment and Management of Contaminated Sites—Draft Policy Framework* , National Health & Medical Research Council, Canberra 1997; enHealth, *Health Impact Assessment Guidelines*, Commonwealth of Australia, Canberra 2001.

[39]For instance risk analysis (particularly risk assessment) provisions can be found in the following acts, *Environmental Protection (Impact of Proposals) Act* 1988 (Cth); *National Food Authority Act* 1991(Cth); *Occupational Health And Safety (Commonwealth Employment) (National Standards) Regulations* 1994(Cth).

to a variety of subject matters, ever since. However, until recently, the nomenclature assigned to each of the steps of the risk analysis process tended to vary quite substantially, with the same stages being referred to differently in various regulatory regimes and guidelines.[40] For example, whist the overall process of governing risk was entitled 'risk analysis' in the Red Book and the evaluation of the potential adverse exposure to hazard entitled 'risk assessment' [see 7.1.1] in Australia the overall process was often referred to as 'risk assessment'.[41] In some instances the evaluation of the potential adverse exposure was entitled 'risk analysis'[42] in Australia, but in others it was (and still is in some instances) referred to as 'impact assessment'.[43]

The confusion is exacerbated by the fact that many in the corporate sector use the three stage model to determine the safety and efficacy of their products as well as their marketability and regulatory potential. The body which develops and streamlines these business practices is *Standards Australia* (a non-governmental corporate entity).[44] It refers to the overall process as 'risk management', which, as noted above [see 7.1.1] was the second stage within the overall process according to the Red Book.[45] To make matters worse, this corporate 'risk management' standard has been adopted by some state governments.[46]

Quarantine Act 1908 (Cth); *Financial Services Reform Act* 2001(Cth), *Environment And Heritage Legislation Amendment Act* 2000 (Cth); *Year 2000 Information Disclosure* Act 1999 (Cth); *A New Tax System (Goods And Services Tax) Regulations* 1999 (Cth).

[40] National Health Partnership, *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia, 2002 p xi.

[41] Beer T, Ziolkowski F, '*Environmental Risk Assessment: An Australian Perspective*, Supervising Scientist Report 102, Environment Australia, Canberra. 1995. p 3.

[42] "In American usage … risk assessment was the component of the overall process devoted to the calculation of risk and risk analysis was the overall process including risk assessment. In Europe (as in Australia) risk assessment is understood to be the overall process" *ibid.*

[43] EnHealth, Health Impact Assessment Guidelines, Department of Health and Aging and Health Council, Commonwealth of Australia, 2001.

[44] Information about Standards Australia can be found at <http://www.standards.com.au/> (14/2/03).

[45] See Standards Australia, *Risk Management*, Standard(AS/NZ 4360), Standards Australia, Sydney, 1999.

[46]See Broadleaf Capital International, *The Australian and New Zealand Standard on Risk Management, AS/NSZ 4360:1999*, Tutorial Note, Broadleaf Capital International, Pymble (NSW), 1999, p 1.

7.1.4 THE NATIONAL HEALTH PARTNERSHIP

In 1996 the Commonwealth and State Governments agreed to establish a multilateral partnership to national approach to public health (the National Health Partnership (NHP)).[47] The partnership is intended to coordinate, streamline and focus approaches to public health and safety so as to ensure that a 'best practice' approach can be 'asserted and implemented' nationally.[48]

One of the main focal points for the national health partnership was to establish a unified national approach to regulatory oversight of 'environmental health risk' so as to provide for 'efficient, accurate, timely and transparent decision-making and a greater consistency of environmental health decision making across Australia'.[49] So far this body has concentrated mostly on risk assessment and to a lesser extent risk communication, whilst only defining risk management. However, in doing so, it has set the benchmark for the overall approach to making risk decisions. This benchmark is now set out in the NHP *Guidelines For Assessing Human Health Risks From Environmental Hazards* 2002 (the NHP Guidelines).[50]

Although the NHP Guidelines were created after the GTA, they reflect the standardised best practice in Australia to dealing with public environmental health risk. As noted above [see 6.3.3] the GTA encourages the Regulator (more aptly the Office of the Gene Technology Regulator) to adopt such standards in its evaluation of risks. The NHP guidelines, along with international standards will then be influential in the ongoing process of risk assessment and management of gene technology.

The NHP Guidelines describe the NAS-NRC Red Book as 'a particularly influential as a template'[51] and hence the Australian benchmark is 'based largely

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[47] Memorandum of Understanding Between: The Commonwealth of Australia; New South Wales; Victoria; Queensland; South Australia; Tasmania; Northern Territory; Australian Capital Territory; Western Australia; To Establish A National Public Health Partnership For Australia, 1996.

[48] *ibid.* Preamble.

[49] National Health Partnership *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia 2002, p vii.

[50] *ibid.*

[51] *ibid,* p 3.

on the National Academy of Sciences model (1983) [the Red Book] with the addition of a preliminary step, "Issue Identification"'.[52] The NHP model uses the same terms as the Red Book (risk assessment, risk management) and the later NAS-NRC report (risk communication) to describe each aspect of the process. However, it avoids using the term 'risk analysis' as an umbrella description of the overall procedure.

7.1.5 THE GENE TECHNOLOGY ACT (OGTR RISK FRAMEWORK)

Under the GTA the Regulator has the power to set out technical and procedural guidelines in relation to GMOs and to provide public information on the regulation of GMOs to the public.[53] Pursuant to this power the OGTR has released a set of guidelines entitled *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator* (the OGTR Risk Framework).[54]

The OGTR Risk Framework is intended to 'assist organisations and individuals who intend to make an application under the Gene Technology Act 2000 or who otherwise have an interest in the potential for, and assessment of, risks from GMOs'.[55] The framework recognises that there are a wide variety of factors which contribute to a classification of risk and therefore only claims to set out a broad framework for risk assessment and risk management.[56]

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[52] *ibid,* p 4.

[53] s. 27(d),27(f), GTA.

[54] This was released in January of 2002. Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator,* Office of the Gene Technology Regulator, Canberra, 2002. The document can be found at <http://www.ogtr.gov.au/pdf/public/raffinal.pdf> (24/12/02). Itis intended to "provide a simple, clear guide to the provisions of the legislation that relate to licensing and related risk assessment and management; · assist applicants for licences (usually Accredited Organisations) by providing a broad outline of the framework used by the Regulator when undertaking risk analysis and the preparation of risk management plans for applications under consideration; provide a transparent and consistent risk analysis process for applications for licences; and · inform the community about the broad framework that is to be used, ensuring that the risk analysis process is also transparent to the broader community." *ibid.* p 2.

[55] *ibid* p 1.

[56] *Ibid.*

Whilst the OGTR Risk Framework never explicitly refers to the NAS-NRC 'Red Book', nor the international treaties or guidelines which implement it, it applies that model and uses the same terms to describe each stage of the risk analysis process. Thus, the overall process is referred to as 'risk analysis' and the sub components are 'risk assessment', 'risk management' and 'risk communication'.[57] Like the NHP Guidelines it creates an additional identification step, but terms it 'hazard identification', rather than 'issue identification'.[58]

The OGTR recognises that the parameters of risk analysis are constantly being revised, perfected and streamlined.[59] Thus the OGTR explains that the risk framework provides only a general guidance[60] to the process and that it 'will be revised as experience develops and best international practice changes'.[61] It would seem, then, that the international standards,[62] followed by the domestic standards (NHP Framework)[63] would be more legally biding than this framework. However, as the OGTR notes, the framework merely applies these external sources to the specific 'legislative arrangements' of the GTA.[64] Thus, the following discussion will take into account all these sources, not just the OGTR framework, when considering the scope and implications of risk assessment and risk management.

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[57] "The Gene Technology Act 2000 makes specific reference to risk assessment and to risk management plans. It also has extensive provisions concerning risk communication. To avoid confusion between the specific processes of risk assessment, risk management and risk communication, the collective term used in this document for these three activities will be risk analysis." *ibid,* p 2.

[58] "the very first step (some would even say prior step) of a risk assessment is hazard identification. For clarity, hazard identification will be described as if it is a separate prior step, although risk assessment as used in the legislation implies hazard identification as an intrinsic part – one cannot undertake a risk assessment without it. Consequently, the risk assessment prepared by the Regulator will include identification of the hazards." *ibid.* p 2.

[59] "Risk analysis by the Regulator obviously occurs within a regulated framework, but there are also parameters of good scientific practice and good administrative practice that shape the process to some extent. Key parameters are outlined for the guidance and information of applicants and others." *ibid,* p 15.

[60] *ibid,* p 1.

[61] *ibid,* p 15.

[62] Because they are annexed or ancillary to international treaties such as SPS and TBT [see 7.1.2 (text)].

[63] Because it is formed under a intergovernmental compact – the Memorandum of Understanding *op cit* 47.

[64] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator*, Office of the Gene Technology Regulator, Canberra, 2002. p 15.

7.1.6 RISK GOVERNANCE

There has then been some normalisation of the terminology used to denote risk practices in Australia. However, I wish to introduce a fourth term, because I believe that some confusion remains in the community about these processes, their overlap and who undertakes them (i.e. government or industry). That term is 'risk governance', and was originally proposed by the European Community to describe the overall process of *regulating* risk – as distinct from risk measures taken by non-regulatory bodies.[65] Risk governance may utilise risk analysis as a regulatory device, or it may use another process (such as Environmental Impact Assessment, self-regulation, prohibition etc)[66].

I will use risk governance from this point on to describe the overall strategy used to regulate risk by a governmental agency, without reference to the internal structure itself. Thus, the GTA can be described as a risk governance framework – even though it does not refer to itself as such. However, because the GTA adopts a Red Book risk analysis model as the internal structure of that risk governance process, I will continue to use the nomenclature adopted in that report (risk analysis, risk assessment, risk management and risk communication)

7.2 THE RISK ANALYSIS PROCESS

As explained above, the accepted model for the risk analysis process has three main pillars: risk assessment; risk management; and risk communication. Each of these pillars has its own processes and protocols attached to it. These will be examined in further detail below. In setting out the general process, it must be realised that there is no completely standard approach to risk analysis. However, many of the fundamental steps and practices do tend to be accepted across all international and domestic risk analysis systems. It is important to understand

[65]Discussed in European Communities Committee(UK), *EC Regulation Of Genetic Modification In Agriculture European Communities*, 2nd Rept, 1998 - 99, HL Paper 11-1, The Stationary Office, London 1999, p 85.

both the shared features of these various systems as well as those aspects which might vary to build a better picture of how rigidly a risk analysis framework should or will be applied within a risk governance regime such as the GTA.

7.2.1 RISK ASSESSMENT

Risk assessment is described by the OGTR as:

> the process of estimating the potential impact of a hazard on a specified human population or the environment under a specific set of conditions within an identified timeframe.[67]

The National Health Partnership (NHP) Guidelines [see 7.1.4] provide a much broader definition based on the Red Book model:

> Risk assessment is the process of estimating the potential impact of a chemical, physical, microbiological or psychosocial hazard on a specified human population or ecological system under a specific set of conditions and for a certain timeframe.

It is worth highlighting the recognition of broader factors such as 'psychosocial' hazards in this definition. The SPS definition, on the other hand, is much more technical:

> The evaluation of the likelihood of entry, establishment or spread of a pest or … according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health …[68]

Here 'economic' hazards are also included as part of the risk assessment.

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[66] Lawson suggess that risk assessment in the GTA is replaced with either 'environmental impact statements … insurance … ecologically sustainable development … cost to benefit analysis' Lawson C 'Risk Assessment in the Regulation of Gene Technology' (2002) Environmental and Planning Law Journal **9**:214.

[67] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator*, Office of the Gene Technology Regulator, Canberra, 2002, p 12.

[68] annex, A.4, SPS.

The ultimate aim of risk assessment is to provide a formulaic decision tree, which follows logical systematic steps. The risk characterisation stage, at which an evaluation is made, is only a final step when a quantifiable outcome is satisfactorily reached. That is, the process is recursive to the extent that should new hazards or concerns be identified in the last stage, the process will be re-initiated and refined.

The Red Book split up the process of risk assessment into four steps. These are *hazard identification, hazard characterisation, exposure assessment*, and *risk characterisation*.

- Hazard Identification : the identification of a hazard, its dangers and impact upon the target population or resource.
- Hazard Characterisation : the evaluation of the quantitative or qualitative impacts of the hazard on the target population or resource.
- Exposure Assessment : the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents;
- Risk Characterization : the qualitative and/or quantitative estimation of the probability of occurrence and severity of known or potential adverse health effects in a given population based on a hazard identification, hazard characterization and exposure assessment, including attendant uncertainties. [69]

Each international agreement described above reflects such a model. However there has been a tendency in more recent frameworks to separate out hazard identification into a precursor component to the whole of the risk assessment procedure. This is found in the International Office of Epizootics (OIE) standards [see 7.1.2], the NHP Guidelines[70] and the OGTR Risk Framework.[71] Separating

[69]See Codex Alimentarius Commission, *Definitions for the Purposes of the Codex Alimentarius* Procedural Manual of the Codex Alimentarius Commission p *44* <the manual may be found at ftp://ftp.fao.org/codex/manual/Manual12ce.pdf> (28/10/02).

[70] National Health Partnership, *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia, 2002, p. 25.

[71]Office of the Gene Technology Regulator, *Handbook to Gene Technology in Australia*, Commonwealth of Australia (AGPS), Canberra, 2002, p 11.

out risk identification streamlines the process making it more cost and time effective. This is because if no hazards are initially identified the remainder of the process need not be undertaken. The OGTR Risk Framework also defines the hazard identification process as a separate component of the overall risk analysis procedure.

7.2.2 RISK MANAGEMENT.

Under the GTA the 'risk management plan' is something, as pointed out by the OGTR, that is undertaken: 'before the project commences'.[72] The OGTR defines risk management as:

> the process of evaluating alternative actions, selecting options and implementing them in response to risk assessments. The decision making will incorporate scientific, technological and any other relevant considerations. For example, the risk management plan will take into account not just the conditions that need to be observed in order to manage risk but also the capacity of the applicant to observe such conditions.[73]

The risk analysis framework documentation does not discuss how issues not identified by risk assessment should be incorporated into the risk management process.

The NHP Guidelines describe it as a:

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[72] Such as training, or upgrading facilities and steps that are taken during or after the dealings, such as storage, transport and handling, field monitoring, inactivation and safe disposal of GM materials after completion of the proposal, and evaluation and reporting of outcomes. It may include requirements for matters such as: the required level of containment in respect of the dealings: actions to be taken in case of the release of a GMO from a contained: environment; the geographic area in which the dealings authorised by the licence may; occur; the degree of supervision and monitoring required by the organisation; contingency planning in respect of accidents or unintended effects of the dealings authorised by the licence; and measures to limit the dissemination or persistence of effects of the GMO or its genetic material in the environment. Pp 23-24.

[73] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator*, Office of the Gene Technology Regulator, Canberra, 2002, p 23.

> broader evaluation of the results of the risk assessment and takes into account not only scientific data, but also social, economic and political considerations.[74]

The Codex Alimentarius Commission (Codex) defines risk management as a*:*

> process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the ... protection of consumers.'[75]

Thus, risk management is intended to take place once all scientific risks have been identified and evaluated. In an idealised risk analysis framework risk management is the realm of policy choices. It is the process by which the agency responsible for the protection against risk, evaluates and designs the course of action to mitigate those risks.[76] This process is multifaceted and multidisciplinary.[77] The outcome of the risk management process is the development of 'guidelines and other recommendations',[78] that the OGTR indicates will assist the 'determination of conditions that are needed to control or lessen the risk and mitigate any adverse events'.[79]

Unlike the clear formula for risk assessment, risk management procedures were not set out in the Red Book. This evidently occurred because that committees mandate was to review risk assessment. The outcome, however, has been much less of a focus on risk management as a structured framework.

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[74]National Health Partnership, *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia, 2002, p xvi

[75] Codex Procedural Manual (FAO/WHO, 1996. Report of the twelfth session of the Codex Committee on general principles. Paris, 25 - 28 November. ALINORM 97/33. Codex Alimentarius Commission. FAO, Rome.), p 46

[76] Ruckelshaus W.D, 'Risk, Science, and Democracy', (1985) *Issues In Science. & Technology* **28**:19.

[77] The Red Book noted that an ideal risk management would take into account 'political, social, economic, and engineering information with risk-related information to develop, analyse, and compare regulatory options and … response'. National Research Council, at 1819.

[78] Codex

[79] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 23.

The Technical Barriers to Trade Agreement (TBT) [see 7.1.2], makes no express mention of risk management. The Sanitary and Phytosanitary Agreement (SPS) [see 7.1.2], whilst defining risk assessment does not similarly define risk management, although it does allow a state to take 'necessary sanitary and phytosanitary measures to protect human, animal or plant life'.[80] However, this provision is circumscribed, insofar as such measures must be justified by scientific evidence and must not discriminate on imports, nor be a 'disguised restriction on international trade'.[81] The Biosafety Protocol does set out several risk management provisions, but these too are geared towards normalising principles rather than setting procedure.[82] For instance, the Protocol requires that risk management measures must occur subsequent to a proper risk assessment, and be justified by and proportionate to those measures. [83]

The lack of a unified, harmonised approach to risk management derives principally from the fact that, by definition, it is an inherently political process and it incorporates a multifaceted number of considerations.[84] However, increased focus upon 'scientifically justifiable' basis for trade measures which result in import restrictions under the WTO regime (pushed primarily by the U.S) has led to moves to streamline and standardise risk management, so that management decisions can be examined reviewed by appellate bodies.[85]

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[80] Art 2.1.

[81] Arts 2.1-2.3 SPS Agreement. States are to base their sanitary and phytosanitary measures on international standards, unless none exist, the ones that do are inappropriate or there is a scientific justification for providing a different standard. [Arts 3.1-3.3] Moreover, standards different than internationally accepted sanitary and phytosanitary measures must be designed to avoid negative trade effects and avoid unjustifiable distinctions between products. [arts 5.1.-5.5]

[82] art 16, Cartagena Protocol on Biosafety 1999.

[83] Arts 16.2-16.3 Cartagena Protocol on Biosafety 1999.

[84] The Redbook, supra at 152.

[85]In the US the lack of a unified system for risk management was perceived as requiring review and in 1996 the US Commission on Risk Assessment and Risk Management was charged with reviewing the risk management approach in that country. It found that 'after many years of management of environmental, health, and safety risks in the United States, there is still no generally accepted or uniformly applied framework or set of principles for making risk-management decisions.' The Commission proposed the implementation of a comprehensive framework to address multifaceted concerns in a unified and logical way. This framework comprised of six stages: 1) Formulate the problem in broad context. 2) Analyze the risks. 3) Define the options, 4) Make sound decisions; 5) Take actions to implement the decisions; 6) Perform an evaluation of the effectiveness of the actions taken. See Presidential/Congressional Commission on Risk

Thus far, only the OIE has implemented a set four stage approach, akin to that of risk assessment. This process requires, *risk evaluation*,[86] *option evaluation*,[87] *implementation*,[88] *monitoring and review*.[89] Other standard setting bodies have tended to focus less on a step by step process but rather echo the broad principles set out under the SPS agreement and Biosafety Protocol. These principles are generally orientated towards ensuring that: the separation between risk assessment and management is maintained; and risk management does not impact on trade.[90]

Assessment and Risk Management: *Framework for Environmental Health Risk Management*, Final Report (Vol 1), US Government Printing Office, 1997, p 1;

In 1995 the OECD established the Working Group On Harmonisation Of Regulatory Oversight In Biotechnology and charged it with fostering regulatory harmonisation of risk analysis frameworks in member countries. In 2000 the working group released its first major report into the status of member countries risk analysis programs. Whilst it recognised a clear cohesiveness in risk assessment processes the Committee cited a clear lack of harmonisation of risk management principles between countries. It called for 'an increased mutual understanding among Member countries of their risk management policies.' The Committee declared it would continue to 'focus on scientific and technical aspects of risk management issues'. Orgainization for Economic Cooperation and Development, *Report Of The Working Group On Harmonisation Of Regulatory Oversight In Biotechnology* (2000) OECD C(2000)86/Add2

[86] The process of comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection. Article 1.3.2.6.

[87] The process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the risk. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of the hazard. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options. *ibid.*

[88] The process of following through with the risk management decision and ensuring that the risk management measures are in place. *ibid.*

[89] The ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended. *ibid.*

[90]The Codex Manual [Codex, *Statements Of Principle Concerning The Role Of Science In The Codex Decision-Making Process And The Extent To Which Other Factors Are Taken Into Account*, CODEX Manual Paris, 2001] Sets out the following principles

Risk management should not impede upon risk assessment … The Codex manual iterates that 'the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment'. It does however recognise that some interactions are essential for a pragmatic approach. However this tends to lean heavily in the direction of risk management, that is that scientific considerations may form part of that process rather than visa-versa. (p 167).

Risk management decisions should be clearly documented, including the rationale for their integration, on a case-by-case basis (p166).

Hence, these principles are more about stating what management practices should be avoided but provide little insight in the decision process that should be adopted. However, as these principles become more formalised and cemented into international practice they will have an increasing effect on how the domestic decision making process is undertaken. In particular, the use of 'precaution', is an area of decision making which will be subject to ongoing debate [see 10.1.3].

7.2.3 RISK COMMUNICATION

Risk communication is the third component of the risk analysis paradigm. Compared with the other two pillars, it has received little attention – at least until recently. Yet, I would argue that it is a core and necessary component of the process, not only because it legitimises it, but simply because it is vital to survival of risk analysis practice. For this reason, risk communication is dealt with extensively in the latter half of this thesis. Thus, I will not enter into any great detail at present, except to give a general overview of the processes.

The most notable point is risk communication is not mentioned in the GTA whatsoever. However, the OGTR emphasises that:

> The Gene Technology Act 2000 makes specific reference to risk assessment and to risk management plans. It also has extensive provisions concerning risk communication.[91]

The OGTR defines risk communication as:

> the process of ensuring that: an open and transparent process of identification of risks associated with (in this case) gene technology and GMOs has been rigorously followed, and; the community is

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The economic feasibility of risk management options may be considered. However where related to economic interests and trade issues they should be substantiated by quantifiable data;. (p 166).

Risk management decisions should not impact upon trade. Particular attention should be given to the impact on developing countries of the inclusion of such other factors. (p 166)

[91] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 2.

> adequately informed about what these risks are and how they are being managed; and public confidence in the regulatory system is maximised.[92]

Similar definitions can be found in relevant international and domestic documents. I will expand upon these in detail in chapter 11.

7.3 THE SCIENCE/POLICY DIVIDE

One of the most dominant features of the Red Book paradigm is the requirement that risk assessment be based solely on scientifically quantifiable data (something quite different from the social perception of risk [see 5.1]). Risk management concerns, according to this principle, should not and should not be seen to affect risk assessment.[93] The NAS-NRC argued that this was necessary, because without epistemologically justifiable outcomes, the 'credibility of the assessment … can be compromised' and the whole decision making process undermined.[94] The perceived need to ensure that risk assessment remains the realm of science has been doctrinally enshrined in the majority of international and national agreements. For instance, Article 2.2 of the SPS Agreement states:

> Members shall ensure that any sanitary and phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence ...

Under the TBT agreement members may only create technical regulations where there is a legitimate objective which is to be assessed by *inter alia* 'available scientific and technical information, related processing technology or intended end-uses of products.' Article 15 of the Biosafety Protocol also asserts that risk assessments should be undertaken with 'recognised' scientific techniques and

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[92] *ibid*, p 14

[93] The Redbook, supra at 152. This is emphasised in the Codex Manual [Codex, *Statements Of Principle Concerning The Role Of Science In The Codex Decision-Making Process And The Extent To Which Other Factors Are Taken Into Account*, CODEX Manual Paris, 2001] for risk assessment.

[94] The Redbook, supra at 152.

based on a scientific evidence. This emphasis on science as the sole or dominant consideration in the risk assessment process has been generally reflected in most countries risk analysis frameworks.[95]

According to the Regulator the GTA also circumscribes risk assessment to only scientific considerations. The Regulator's risk analysis handbook states 'risk assessment is a scientific process that does not take political or other non-scientific aspects of an application to use a GMO into account'.[96]

Because of the emphasis on scientific outcomes the Red Book paradigm tends to utilise quantitative results for any risk assessment process. A quantitative risk assessment process attempts to formulate values to express the degree of risk. However it is generally accepted that this narrow risk assessment strategy is not always feasible. As the OGTR notes, the base values at the core of the assessment are often the product of estimates or assumptions.[97] This is particularly true of a novel technology, where there is little risk data to base evaluations upon. Moreover, the expression of risk will often be a qualitative process. Therefore, qualitative assessments are accepted as alternatives in certain situations.[98]

7.4 A SHARED PROCESS

In describing what risk analysis is, it is also important to understand *who* undertakes the process. Whilst the GTA places the obligation upon the Regulator to 'prepare' a risk assessment and risk management plan, the OGTR is not set up as a scientific agency. Rather it is a regulatory oversight body. This role is somewhat different than in other larger countries where the regulatory agency can

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[95] Power M, McCarty L.S. 'A Comparative Analysis of Environmental Risk Assessment/Risk Management Frameworks' (1998). *Environmental Science and Technology*, **36:**224-231.

[96] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, 12.

[97] *ibid*, p 21.

[98] For the OGTR these include: expert opinion; · public consultation; published material on analogous situations and
experience or advice from other regulatory agencies. *ibid.*

sustain its own scientific arm.[99] Hence, it is actually the licence applicant who undertakes a large proportion of the assessment itself. I will examine the extent of the cooperation between regulator and applicant in respect of both risk assessment and risk management separately.

7.4.1 RISK ASSESSMENT

The *Gene Technology Regulations* 2001 (Cth) (the Regulations) allow the Regulator to specify what technical or scientific data must be submitted as part of a licence application. The Regulations are currently extremely comprehensive and set out a large number of details relating to the organism which must be included dependent on its taxonomy and parent organisms.[100] However, it is not only the responsibility of the applicant to submit data on the organism, they must also assess and evaluate the risks of the dealing.

Under the Regulations the Applicant must assess 'risks that the proposed dealing … may incur in relation to the health and safety of people and the environment'.[101] Such an assessment must be based on 'as comprehensive as existing scientific knowledge, when the application is made, permits; and … supported by whatever relevant data and references are available to the applicant'.[102] The Applicant's assessment must also point out any gaps in the assessment because of incomplete or unavailable information and how 'significant' that gap is.[103] It must then 'evaluate' the possible risks 'based on theoretical approaches, and research methods, that are generally accepted in the scientific community'.

The veracity of the information and the personnel undertaking the dealing must be certified by an Institutional Biosafety Committee within the accredited organisation.[104] This is described by the OGTR as a 'quality assurance mechanism

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[99] For instance the FDA in the United States.

[100] *Gene Technology Regulations* (Cth) 2001, [herein Regulations]

[101] sub.7(2), Regulations.

[102] subs.7(3),7(4), Regulations.

[103] subs 7(4)(b)&(c), Regulations.

[104] sched. 3,prt.1.6. & sched.4, prt.2.12 Regulations.

… to ensure that the information that reaches the Regulator … as comprehensive and accurate as possible'.[105] The Regulator may require further data to be submitted[106] and can if she or he thinks fit, 'outsource' part of the assessment to another body.[107] Based on the information provided, the Regulator undertakes the 'final' assessment which is basically a scrutineering of the risk data and risk assessment provided by the Applicant.

7.4.2 RISK MANAGEMENT

In Chapter 9, I will examine how the Regulator's discretion to set risk management standards is both empowered and prescribed by the Act. It is however, worthy of note that the Applicant partially contributes to the risk management process, albeit to a lesser degree than their involvement in risk assessment.

Under the Regulations the Applicant is required to submit information relating to various operational standards predetermined as necessary components of risk management by the Regulator.[108] However, the Applicant is also obliged to propose their own management strategies. Such proposals are to include: ways of monitoring new and identified risks; limiting transgenic spread; detecting transgenic spread; the best way of transporting GMOs; supervision and training of staff; informing the public of the activity, contingencies for emergencies and how ongoing monitoring should take place after the activity is over.[109] The Applicant is further required to consider any other 'details of other actions and precautions proposed to be taken by the applicant to minimise any risks posed by the proposed dealing or dealings'.[110] These management proposals form part of the information submitted to the OGTR by way of an Institutional Biosafety Committee [see 4.5].

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[105] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p 8.

[106] s.42, GTA

[107] sub.47(e), GTA.

[108] sched.3, prt.1.1.4 Regulations.

[109] sched. 4, prt.2.1.7 & sch. 3, prt.1.14, subs (d)-(f) Regulations.

[110] sched.3,prt.1.1.4 , sub (f), Regulations.

7.5 CONCLUSION

Whilst there is no universal approach to risk governance – indeed the proliferation of various standard setting bodies is intended to create differing approaches – there can be said to be a near unanimous acceptance of the skeletal framework established by the Red Book. This three pillar paradigm (risk assessment, risk management, risk communication), has come to dominate the process of risk governance in Australia as it has elsewhere. The continued harmonisation with international practices will mean that the process of regulating gene technology, like other risks, will increasingly fall in line with the interpretation given to the Red Book paradigm by international standard setting agencies.

The acceptance of the Red Book paradigm brings with it certain structural approaches, institutionalised assumptions and a specialist lexicon of its own. It is therefore important here to reiterate the questions asked at the outset of my discussion of risk, but this time in terms of a better understanding of the meaning of risk applied within the GTA regime.

- Does the notion of 'risk', as accepted under the Red Book paradigm, accord to what those drafting or calling for the GTA understood risk to be?
- What are the implications of applying a normative Red Book approach to the governance of risk?
- Does the application of the Red Book approach change the ambit of what is regulated to something broader or narrower than was originally envisioned?
- Most importantly, how does the standardisation of the notion of risk affect the way decisions are made?

I will attempt, over the next two chapters to answer these questions with specific reference to the application of the risk analysis paradigm within the GTA.

8

RISK ANALYSIS AND THE RISK DILEMMA

The standardisation and internationalisation of risk analysis is leading to the creation of a formalised discipline that has risk at its core. This discipline is the realm of scientists and technical experts both nationally and internationally. They have created a process with general rules, definitions, nuances and assumptions. Risk assessment in particular, has been subject to continued refinement in an effort to create definitive, transparent and justifiable reasoning processes. This is aimed at ensuring that the most effective risk models are presented to risk managers, in order that decisions are made with a proper understanding of the science and the risk.

At the heart of the risk analysis model is the premise that the measurement of 'risk' should be the realm of science, so that it is not clouded by socio-political factors, ignorance or fear. It ensures that concerns about the impact of science and technology are scientifically based and technically defensible. There are several benefits to this model which I will expand upon below.

Subjecting Science to Science. In chapter 5 I argued that the risk dilemma was exacerbated by modern technology because that technology is extremely complex, highly technical and that 'technology constantly restructures and reinvents itself'. The risk analysis model eases this dilemma, because it subjects the science *to* science. That is, whilst the subject matter is constantly changing so is the method

of evaluation. This ensures that risk governance processes are as dynamic as the subject matter they oversee.

A Better Picture of 'Actual' Risk. The risk analysis paradigm is designed to distil political decisions from scientific ones, so that each may be examined separately.

> The importance of risk assessment lies not only in its capacity for estimating human risk, but also in its function as a framework for organizing data as well as for allocating responsibility for analysis.[1]

By separating out science from policy, decisions made by officials can be better subject to scrutiny and review. That is, scientific grounds are identified as scientific. They can objectively be peer reviewed, tested and critiqued. Political and social decisions are separated out so that they can be subject to political and social review. Risk analysis then, is intended to reveal what the actual risks are, by ensuring that they are not coloured by subjective or politically determined motivations.

Separating out the processes of risk assessment and risk management from each other allows a greater level of transparency. It also ensures that the overall process can be constantly fine tuned and perfected. Because the various parts of the decision making process are compartmentalised, they may be later examined for fault should a deleterious outcome emerge. Indeed, the volumes of critique about the risk analysis process could only have arisen by virtue of the categorisation and documentation of the process, which facilitates of peer and social review. These criticisms can be taken on board and utilised to improve the system. The capacity for reform is an important element in ensuring that regulatory frameworks successfully exercise control over technology.

Informing the Decision Maker. I have emphasised that the risk dilemma is about taking control of technology to ensure that it is government who has the ultimate

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[1] Food Quality and Standards Service Food and Nutrition Division, *Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System,* Food And Agriculture Organisation Of The United Nations, Rome, 1998, Annex II.

power to decide the fate of the people. Taking power of technology means not only minimising its risks but *using it* to minimise risks and to promote the benefits technology might provide. To undertake such a task, and to have complete power over the technology, those charged with making such decisions must truly understand it. Yet, decision makers are rarely experts, and even when they are (as is the case with the current Regulator [see 9.4.1]) they are unlikely to have a complete level of knowledge of a discrete area of science, new technique or technologies. Risk assessment allows risk management decisions to be informed. It does this by taking highly technical and complex data and translating it into a form which a decision maker can understand and utilise. As the National Health Partnership (NHP) Guidelines state:

> the ultimate aim of risk assessment is to provide the best possible scientific, social and practical information about the risks, so that these can be discussed more broadly and the best decisions made as to what to do about them.[2]

Risk assessment is then the cornerstone of modern risk governance because it reaches right into the heart of the scientific endeavour, extracts information from it and moves it up the chain to the decision maker. It ensures that regulatory intervention is educated, informed and effective.

8.1 A NARROW DEFINITION

There seems little point reiterating that any choice of law or system of legislating has both positive and negative aspects. Risk analysis also presents problems. The first, and perhaps most apparent from previous discussion is that it is a much narrower, or at least more dichotomised, definition of risk than might be accepted in the general community.

[2] National Health Partnership, *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia, 2002 p xi .

By creating a dichotomy between science and policy, there is an implication that anything that cannot be mathematically or physically assessed is not a risk. The other interpretation is that the 'non scientific' concerns brought in during the management phase are still 'risks' (hence the retention of the term 'risk management') but that they are not capable, some may argue 'worthy', of methodological scrutiny. Even if the latter interpretation is accepted, these risks are seen to be 'lesser' risks. This is because those risks that have been identified in a established methodological, systematic risk assessment will tend to appear more sound than ones that have not.

Some critics argue that the science/policy dichotomy leads risk experts to believe any 'non scientific' concerns to be based on 'subjective, often hypothetical, emotional, foolish, and irrational' grounds.[3] It is easy to see how such criticisms arise given the nature of the development of the risk analysis paradigm. Risk assessment has undergone positive development and refinement with the intent that it should continually enshrine 'best practice'. Conversely, the rules relating to risk management have been less orientated towards creating a systematic approach. Rather, they are generally negatively constructed, so as to ensure that unjustified and unfounded concerns and/or other disguised restrictions are avoided. They could be seen as a process built up with the intent to avoid 'worst practice'. Yet, it is in the risk management phase that the non-scientific risks enter into the decision making process. When viewed from this perspective, it seems that scientifically based concerns are being built up and fortified while non scientific concerns are being denigrated, restricted and confined.

Narrowing Of 'Science'. What is also clear is that there is a potential for selectivity as to what can be 'scientifically' examined. This is evidenced in the three definitions of risk assessment outlined in the previous chapter (Codex, NHP Guidelines and OGTR Risk Framework) [see 7.1-7.2]. Under the domestic NHP Guidelines, non physical factors such as 'psychosocial' impacts are included as potentially 'assessable' risks. The international Codex guidelines adopt a narrower more quantifiable basis for risk assessment, but it still includes the non-physical

[3] Kunreuther H, Slovic P, "The Process Of Risk Management: Science, Values, And Risk' (1996) *The Annals of The American Academy of Political and Social Science* **545**:116.

'economic' consequences as an 'assessable' risk. Finally, the Office of the Gene Technology Regulator (OGTR) implements the most rigid and narrow definition of what risks are 'assessable', being only those physical impacts on human populations or the environment within limited timeframe and conditions. In the OGTR Risk Framework, psychosocial and economic concerns do not merit scientific evaluation.[4]

The position of the OGTR is perhaps a result of a regulatory framework in which ethical and community concerns are not clearly integrated into the risk analysis paradigm. The Regulator is advised by three different expert committees, being science based, community based and ethics based. There is then, an institutional separation between science, ethics and community concerns. One scientist highlighted this during inquiries into the Gene Technology Bill, arguing:

> if you really want ethics to infuse the whole debate, why not thoroughly integrate the so-called ethics committee, or the ethicists that are involved, in both the technical committee and the community committee. Why have a separate entity? If anything it reinforces the public view that ethics is over here and scientists are over here and the twain never meet.[5]

Given concerns about such divisions the Government amended the original Gene Technology Bill so that a member of the ethics and community committees now sit on the science committee and *visa versa* [see 4.4]. Nevertheless, the divide remains entrenched, not least because the science committee is the only committee which *must* be consulted on every licence application [see Appendix 1].

The process of drafting will be discussed later, but it is worth pointing out here that the basic risk analysis framework was decided upon before the Gene

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[4] A fact confirmed by the list of information requirements in the OGTRs risk manual. see generally, Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, part 2.

[5] Roush B, 'Community Affairs References Committee: *Gene Technology Bill* 2000: Discussion', *Community Affairs References Committee Hansard,* 22/8/2000, p 101.

Technology Bill was released for consultation [see 14.1]. What seems to have happened is that a rigid science based process of risk analysis was adopted from the outset, with drafters then attempting later in the piece to reshape it, so as to allow for ethical and community concerns to become part of the process (for instance see 15.2 for a discussion of the creation of the Community Committee). This 'extension' of the conventional risk assessment framework was recognised in the Explanatory guide to the Gene Technology Bill. It stated:

> The inclusion of ethical considerations goes beyond the conventional risk assessment framework, continuing a science-based approach for risk assessment, but also including capacity for formal consideration of broader issues such as ethics.[6]

There are two problems with this statement. First, it is unclear whether the drafters when talking about a 'conventional risk assessment framework' were actually referring to risk analysis, or whether they in fact were imputing that 'broader issues such as ethics' would in fact be considered as part of the risk assessment process. This would seem the case until later in the guide the risk assessment is described as including 'a risk analysis and a risk evaluation'. It seems that the confusion in Australian terminology [see 7.1.3] had not been totally resolved at this stage, so little conclusive evidence one way or the other can be drawn from the above statement.

The second problem with the above statement is that there seems to be an intentional separation between 'risk' as science and 'ethics' as 'issue'. At this point the Community Committee had not been incorporated into the regime, but looking at the final Act would seem to indicate a reticence by the drafters to equate ethics or community/social impacts with risks. At no point does the Act use the term 'ethical risk', but rather 'ethical issues'.[7] Similarly the Community Committee is charged, not with examining 'social risks' or 'risks to the community' but 'matters of *general* concern [emphasis added]'.[8] General matters

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[6] Interim Office of the Gene Technology Regulator, *Explanatory Guide to the Gene Technology Bill*, Commonwealth of Australia (AGPS), Canberra, 2000, p 10.

[7] subs.21(1)(a), 112 (a), GTA.

[8] sub.107(aa),107(a), GTA.

cannot be subject to methodological testing and evaluation. Rather the phrase implies that they are transient, esoteric and indeed 'generally raised'.

Despite the reluctance of the legislature to directly state that ethical and community concerns were risks *per se* there is cause to argue that the Act should be interpreted to include these components within the overall definition of risk. The GTA is a *risk regime,* its purpose is to protect against 'risks posed by or as a result of gene technology'. The objects clause *does not* contain any term that provides for other 'non-risk' issues or concerns. It does not require the 'management of risks *and ethics and other community concerns*', but simply that the sole purpose of the act is to manage risks posed by gene technology. We must read the context of risk in the objects clause with reference to the Act as a whole. The Act permits the Regulator to consider ethical and community matters (hence the committees relating to these areas). In making a decision Regulator is required to consider 'risks … *including* [emphasis added] any risks to the health and safety of people or risks to the environment'.

There is uncertainty about the term 'includes', in that it could be taken as exhaustive.[9] However the phrase has often been taken to connote an open definition, intended to enlarge the meaning of the word it follows.[10] It we take the former to be the case, there would be little point in constituting the Community Committee and the Ethics Committee with such a broad range of members with non environmental and non human safety expertise.[11] Concerns about the treatment of animals in laboratory experiments, the impact of gene technology on the community, or religious practices, do not fall under the classification of either harms to the environment or harms to humans. However,

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[9] *YZ Finance Co Pty Ltd v Cummings* [1964] ALR 667.

[10] *Dilworth v Stamps Commissioner* [1899] AC 99, at 106; *Marsal Pty Ltd v Comptroller Of Stamps* (VIC) (1982) 82 ATC 4, 536; *R v MCN* (1963) 63 SR 186.

[11] These include, with relation to the Ethics Committee: ethics and the environment; health ethics; applied ethics; law; religious practices; population health; agricultural practices; animal health and welfare; issues of concern to consumers in relation to gene technology; environmental systems. [sub.111(5), GTA.] With relation to the Community Committee: environmental issues; consumer issues; the impact of gene technology on the community; issues relevant to the biotechnology industry; issues relevant to gene technology research; public health issues; issues relevant to primary production; and issues relevant to local government.

the fact that these committees exist seems to bring such concerns under the umbrella of risk as defined in the Act.

8.2 THE BROAD PUBLIC/NARROW EXPERT CONFLICT

Despite an implied recognition that ethics, community, social, economic and 'other' concerns fall under the ambit of 'risk' under the GTA, they remain 'lesser risks' because they have been diminished in importance by the structure of the Act, and excluded from risk assessment by the approach adopted by the OGTR. Slovic argues that such black and white dichotomies and ranking of 'legitimate; scientific risks against indeterminate public 'perceptions', fundamentally disregards the 'technical, social, and psychological qualities of hazards that are not well-modelled in technical risk assessments'.[12] That is, they fail to 'appreciate the complex and socially determined nature of the concept "risk"'.[13]

The public clearly has broader perceptions of risk in relation to gene technology [see 2.3]. Concern about the impact of gene technology to human health and the environment in the community is strong but people are also concerned about potential ethical, moral, economic and social hazards. However, such hazards are not afforded the intensive, comprehensive and systematic approach taken with respect to 'physical hazards'. Instead the ethics and community committees are primarily charged with creating overarching policy principles or guidelines which are intended to ensure that ethical or community harm is avoided. As will be discussed later [see 10.3-10.4], these are not undertaken on a case by case basis, but are set in advance of regulatory activity. There seems to be an assumption here that these committees can see through the regulatory fog, to second guess the technology and determine the impact of future gene technology applications.[14]

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[12] Slovic P, 'Perception of Risk', (1987) *Science* **236:**280.

[13] Slovic P, 'Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield', (1997) *University of Chicago Legal Forum* **59**:61.

[14] Whilst there may be some fundamental or social principles which should never be breached, others are likely to be more ambiguous. For instance it may seem clear that creating human/animal hybrids is morally reprehensible. Yet it has also been relatively well accepted that inserting human genes into goats to produce albumin (for surgery, trauma, and burns) in their milk is acceptable. Where is the line to be drawn between these two transgenic technologies?

This is not exercising a complete control over *all aspects* of the technology, even though these broader aspects are part of the risk dilemma which necessitated risk governance in the first place.

What must be realised is that while the science/policy dichotomy in a way undermines the risk dilemma, it is also partly a result of it. In the blame society we may see the wider social implications of technology as deleterious, but we also see technology as a solution (if it is properly controlled). The blame society is then partly responsible for putting technology on a pedestal. Hence:

> [p]art of the problem with risk assessment is that we think of ours as a scientific and technological society. We have come to trust numbers and believe that "mathematic precision" and "statistical significance" are important just because they are "precise" and "significant".[15]

Thus, a culture has grown up which seeks to separate out science from other disciplines, doctrines or concerns because science enlightens and non-science obfuscates. This is evident in the express principles set out in the risk analysis paradigm throughout the domestic and international frameworks described above. Such attitudes also underlie many of the debates over the GTA. Several Government parliamentarians warned that the GTA should be based on 'good science' or 'sound science' and not on driven by 'irrational' or 'politicised or 'ill-informed sensationalism', by those with an 'ideological bent', or become a 'charter for luddites'.[16] Hence, science was cast as 'good' (literally) and ethical, social or moral concerns as 'bad'. From the language used in these debates it would appear that often the very basis for maintaining a science/policy dichotomy is somewhat personal and value based. As Jasanoff states:

> Should risk management (what we wish to do about risk) be allowed to influence risk assessment (what we know about risk)? The very

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[15] McElveen J, Amantea C, 'Risk Symposium: Legislating Risk Assessment' (1995) *University of Cincinnati Law Review* **63**:1579.

[16] Washer M, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 28/8/2000, p 19463;; Eggleston A, 'Gene Technology (Consequential Amendments) Bill … Second Reading', *Senate Hansard*, 7/11/2000, p 19302.

> idea is anathema to environmental policy makers who came of age in the 1980s. It is like asking whether politics should control science. We are reminded of Galileo bowing to his inquisitors ...
>
> Trained to think of science as value-free, we believe that the inevitable result of subordinating knowledge to politics must be the corruption of both.[17]

Crying Wolf. The effect of the blame society coupled with the rise of 'risk experts' and their increasingly reductionist view of risk is to diminish the value of non-scientific, non-physical risks in any debate over technology. Therefore, whilst people's conceptualisation of risk is often based on 'richer'[18] and broader grounds than that of experts, they will often attempt to present such concerns as being scientific or physical in nature whether or not they actually are.[19] Others defend their social, moral or ethical judgments by premising them with physical, scientific arguments. Hence, 'GMOs present real threats to health, safety and the environment *and they also* raise ethical issues [emphasis]' was commonly heard in the Parliament.[20] I also believe it explains why some opponents to GMOs will

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[17] Jasenoff S, 'Relating risk assessment and risk management: Complete separation of the two …' (1993) *EPA Journal* 1:**19**:35.

[18]Slovic and McGregor describe lay peoples conceptualisation of risk as being 'much richer than that of experts'. Slovic P, MacGregor D. M, *The social context of risk communication*, Decision Research Report No. 02-06, Oregon, 1994. p 8.

[19] The cloning debate is a good example of this, where hidden beneath the debate about the 'safety' of cloning, are moral absolutes about whether the destruction of an embryo is morally acceptable or not. Yet people will argue about its safety or efficacy, and add in their opinions about the status of the embryo as ancillary to these concerns, even though this moral basis is the central, dominant and often sole concern they have. Parker argues that this allows 'spokespersons for differing positions often do not concede all the implications of their arguments, can sidestep the real moral issues, and fail to be clear about the metaphysics upon which their arguments and policy advice ultimately rely'. Parker M, 'Pluralism And Metaphysics: How Should We Reason About Embryos, Cloning And Stem Cells?', Paper Presented to the AIHLE 7th Annual Conference, University of Newcastle Australia, 27/6/2002, available from AIHLE website <http://www.law.unimelb.edu.au/aihle/> (3/3/03).

[20]For instance: "There are some great opportunities for this country but there are also some issues that have to be addressed in the future. Beyond that there also is a range of ethical issues …" [Griffin A, *Gene Technology Bill* 2000: Consideration Of Senate Message' House Hansard, 7/12/ 2000, p 23816]; "There needs to be a strategy to ensure the isolation of GM crops from non-GM crops. Another issue to be addressed is the use of herbicides. There is also a whole range of ethical issues ..." [Ripoll B, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19558.] ; "In this era of rapid scientific change, there is potential for

entertain rather unconventional scientific arguments, (or what GM proponents call 'junk science') in order to fortify their position against genetic technology.[21]

Thus, arguments about the physical risks will often hide moral judgments because they are assumed to garner more weight if they are articulated in scientific terms. When the scientific claim is proven to have little merit the whole argument fails – despite the fact that the person may have had legitimate, ethical or social underpinnings. The result is to make such claimants appear to be crying wolf about the technology and their concern discounted as baseless. Yet, what they may in fact be responding to is the a legitimate ethical objection to some or all implications of the technology, or a fear about the social risk it poses. The result may be to leave those who have 'cried wolf' disenfranchised, feeling 'powerless' and believing that government is not willing to intervene on their behalf.

8.3 A FALSE DICHOTOMY

I previously argued that the separation between science and policy was given rise to by the advent of the blame society [see 5.2.2]. The result has been the development of a culture that tends to elevate anthropocentric, physical and scientifically quantifiable risks over all others. It is perhaps this aspect of the risk analysis paradigm that has received the greatest criticism. Opponents and critics

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an almost anti-science attitude in the consumer marketplace, for a degree of concern about scientific advances and the efficacy of them, and for an ethical debate around them." [Martyn E, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 28/8/2000, p 19459] ; "Further, it delivers science based decision making with a world first capacity to take into account ethical and community considerations, but in a way that ensures that the decisions are objective and not swayed by interest or lobby groups." [Larry A, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 30/8/2000, p 19616.] "As well as these scientific, health and environmental issues, others have expressed real concern about ethical, social and moral issues." [Bailey F, *Gene Technology Bill* 2000 … Second Reading' House Hansard, 29/8/2000, p 19548].

There were some exceptions to this rule. This is when debate focused on the ethics committee, or on anthropocentric like human cloning (led up by independent Senator Brian Harradine). The minor parties also tended to focus more on ethical and social concerns as being primary rather than subordinate issues, but particularly Democrats leader Senator Natasha-Stott-Despoja who argued that ethical, social and scientific concerns were intangibly related and should be dealt with on an equal footing. [see for instance Stott-Despoja N '*Gene Technology Bill* 2000 … In Committee', *Senate Hansard*, 1/12/ 2000, p 20460.]

[21]Yaren K, 'Trade And Genetically Modified Foods: Frankenfears: A Call For Consistency', (2001) *Asper Review of International Business and Trade Law* **1**:155-157.

of risk assessment methodologies assert that the separation between science and policy is merely a social myth, and the idea of 'value free' risk assessment mere scientific sophistry. For instance, Covello and Merkhofer argue:

> [t]he current state of the art of risk assessment does not permit questions of science to be clearly separated from questions of policy. In practice, assumptions that have potential policy implications enter into risk assessment at virtually every stage of the process. The ideal of a risk assessment that is free, or nearly free, of policy considerations is beyond the realm of possibility.[22]

Critics point out that every part of the risk formula involves some degree of subjectivity and some degree of value judgments.[23] I could hardly deny this argument outright – given that I have previously asserted that risk is a 'guessing game'. Indeed it is this 'guessing game' that critics highlight as the source of a 'politicised' science. McElveen and Amantea argue that scientific decisions always require some degree of political fudging because:

> Proponents of risk assessment claim that the process is scientific and value free, failing to recognize that by choosing to rely on incomplete science, values favouring scientific "guesstimates" are inferred into the assessment. In other words, assessors use values which promote technology over equality or culture.[24]

I wish to examine whether this is in fact the case, and if it is, how it affects the risk dilemma and the way we regulate it.

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[22] Covello V.T, Merkhofer M.W, *Risk Assessment Method*, Plenum Press, New York, 1994. cited in Powell D.A, *et al, Water Warnings: Communication in Drinking Water–Related Public Health Emergencies*, Commissioned Paper 12, The Walkerton Inquiry, Ontario Ministry of the Attorney General, Toronto, 2002. pp 29-30.

[23] Lawson C 'Risk Assessment in the Regulation of Gene Technology' (2002) *Environmental and Planning Law Journal* **9**:204.

[24] McElveen, J, Amantea C 'Risk Symposium: Legislating Risk Assessment' (1995) *University of Cincinnati Law Review* **63**:1553.

8.3.1 SCIENCE, VALUE JUDGMENTS AND SUBJECTIVITY

Really the only thing that science can say with certainty is that it is uncertain. Moreover where technologies are particularly novel, there will really be no way of knowing exactly how much more research should be done to reduce the uncertainty.[25] This leaves scientists and risk experts to draw inferences and conclusions from limited data, because they will never have the full picture.[26] In doing so they necessarily import a degree of subjectivity into the evaluation. Douglas *et al*, assert that this subjectivity is unavoidable, because even the choice to approach the risk assessment with conservatism, is a political decision. They argue that such conservatism:

> can produce highly distorted risk assessments that affect the pattern of regulation, preventing limited resources for health and safety from being efficiently allocated.[27]

Indeed there will always be a reason to question the exact meaning of data, because it is just that, unproven data. The only way to prove it unequivocally is for the hazard to ensue and disaster strike.

Not Science But 'Scientists'. More importantly there is no such thing as unified 'science' capable of making a unanimous decision. Rather there are 'scientists', 'technicians' and 'experts' with a diversity of opinions and interpretations of the

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[25] "Uncertainties in low-dose extrapolation and potency differences across species, within species, and across different routes of exposure complicate estimates of risk and make it difficult to know when enough risk research has been done" Finkel A.M, Golding D, *Worst Things First: The Debate over Risk-Based National Environmental Policies*, Resources for the Future, Washington DC, 1995, p 194.

[26] Jasenoff argues, "careful practitioners of risk assessment have recognized [sic] from the start that theirs is not a purely scientific activity. Indeed, risk assessment is often described as an "art" rather than a "science." The formulation emphasizes that risk assessment, like any artistic endeavor, requires the exercise of subjective judgment. It cannot be done by mechanically followint the rules. Judgment, moreover, must remain sensitive to the policy context." Jasenoff S, 'Relating Risk Assessment and Risk Management: Complete Separation of the Two...' (1993) *EPA Journal* 1:**19**:35.

[27] Douglas D.A, *et al*, *Water Warnings: Communication in Drinking Water–Related Public Health Emergencies*, Commissioned Paper 12, The Walkerton Inquiry, Ontario Ministry of the Attorney General, Toronto, 2002. p 30. see also Ruckelshaus W, *Risk In A Free Society*, (1984) *Environment Law Report* **14**:10.

meaning of data. Just as a range of seemingly contradictory 'expert' opinions can be introduced in a court trial, so can they be introduced into a risk assessment.[28]

8.3.2 OF BEEF AND BUTTERFLIES

When international and domestic rules speak of the need for scientific justification, they rarely define what is meant by 'science', because often, like 'risk' it seems either axiomatic or is mistakenly accepted as a normative technical concept. Yet, just as risk can have a variety of possible meanings, so can science. Various authors have suggested that the science be 'current', 'mainstream', 'quality', 'conclusive'.[29] Of course, all of these adjectives import differing degrees of subjectivity, a fact recognised by the appellate dispute resolution panel of the WTO, in the 1998 *Beef Hormone Dispute*.[30] The panel denied that scientific justification could be proven to be – and thus needed to be – either 'mainstream' or 'conclusive'.[31] Even if science was 'pure' and *could be* value free, the Panel concluded it would never provide a complete picture of risk. This was because risk occurs, 'in the real world where people live and work and die', not just in 'a science laboratory operating under strictly controlled conditions'.[32]

The Beef Hormone Appellate Panel's finding was given direct relevance to genetic modification a year later, when the Monarch butterfly study [see 3.8] became an international news story. The study and the reaction that ensued,[33] revealed that: there is no unified 'science'; laboratory risk is different then 'real world' risk; and the determination of risk is inherently a value judgment.

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[28]Atik argues that risk assessment is 'subject to opinion potentially as varying as the geographic and cultural centers [sic] from which the opinion could emanate.' Atik J, 'Science and International Regulatory Convergence' (1997) *Northwestern Journal of International Law and Business* **17**: 749.

[29] Wirth D. A., 'The Role of Science in the Uruguay Round and NAFTA Trade Disciplines' (1994) *Cornell International Law Journal* **27**:833; Thomas R. D, 'Where's the Beef? Mad Cows and the Blight of the SPS Agreement' (1999) *Vanderbilt Journal of Transnational Law* **32**:497.

[30]Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, Rept. WT/DS26/AB/R, WT/DS48/AB/R, (Jan. 16, 1998), 1998.

[31] *ibid*, at paras 181- 194.

[32] *ibid*, at para 187.

[33] Palevitz B.A. 'Bt or not Bt ... Transgenic Corn vs. Monarch Butterflies' (1999) *The Scientist* 12:**13**:1.

The controversy arose from a short (peer reviewed) paper, by Losey *et al*, in the prestigious journal *Nature*, entitled 'Transgenic Pollen Harms Monarch Larvae'.[34] The Losey paper reported a study into genetically modified corn that had been transformed with genetic material from the bacterium *Bacillus thuringiensis* (Bt).[35] The Bt bacterium releases a natural biotoxin, that acts as a pesticide. It has been favoured as a natural alternative to conventional pesticides. There had been some smaller studies, prior to the Losey study that questioned the impact on non-target organisms. However, they had been inconclusive and Bt, was generally accepted as presenting little risk to non-target organisms.[36]

Rather than study the effects of Bt from the host plant (as previous studies had), the Losey team examined the affect of Bt expressed from the pollen of these plants.[37] In a laboratory assay, the researchers reared larvae of the monarch butterfly on milkweed leaves dusted with pollen from corn modified with the Bt gene. Their results showed that the Bt expressed in corn pollen caused the larvae to grow 'more slowly and [suffer] higher mortality than larvae reared on leaves dusted with untransformed corn pollen or on leaves without pollen'.[38]

The researchers posited that, because corn pollen could travel up to sixty metres from the host, it could be deposited 'on other plants near corn fields and can be ingested by the non-target organisms that consume these plants'.[39] They therefore concluded that, 'corn plants might represent a risk' and 'have potentially profound implications for the conservation of monarch butterflies'.[40] They urged that it was 'imperative that we gather the data necessary to evaluate the risks associated with this new agrotechnology'.[41]

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[34] Losey JE, Rayor LS, Carter ME, 'Transgenic pollen harms monarch larvae' (1999) *Nature* **399**: 214.

[35] *ibid.*

[36] *ibid.*

[37] *ibid.*

[38] *ibid.*

[39] *ibid.*

[40] *ibid.*

[41] *ibid.*

Underlying Values in the Losey Study. The Losey researchers had attempted to temper their conclusions, by arguing only that: risks 'might' occur; they could 'potentially' have implications; and 'further data' was needed. Nevertheless, there is an underlying message of warning in the paper, not least because the monarch butterfly is an aesthetically beautiful, immediately identifiable, highly valued icon of the North American wilderness (their homeland).[42] Hence, the researchers perception of 'risk' was, in part, determined by the value they attached to the natural, cultural and aesthetic importance of the organism in question, values betrayed by their emphasis on the 'profound implications' of their findings, and the 'imperative' need to ensure its 'conservation'. As noted above, the paper was based on a controlled laboratory assay, and thus these conclusions were arrived at with no actual evidence of the affect of Bt pollen on monarchs in the field.

Even though the Losey study was conducted under 'strictly controlled laboratory conditions', it immediately drew a huge amount of attention from the press, academia, environment groups, industry and government worldwide.[43] Whilst previous papers *had* noted the possibility of Bt effect on non-target organisms and micro-organisms, such as beetles, worms, protozoa, and bacteria,[44] they had received little attention outside the annals of academia. This may be because they did not present the same degree of evidence as the Losey study. However, it is more likely because they did not involve symbolic organisms such as the monarch, to which the public (of which scientists are a part) attach a high degree aesthetic or cultural value.

Response to the Losey Study. I have described the public response to the Losey Study previously [see 3.8] and how it came to be an international symbol in the

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[42] Their annual migration from Mexico, through to the United States and Canada is 'one of the best-known spectacles to nature lovers' throughout the region. Yoon C.K, 'Monarch Butterflies Alive and Well in Mexico' *New York Times,* 14/2/ 2003, p A.6; Brunks A.G, 'Captivating Beauty. A Fayette Nursery's Butterfly House has Winged Wonder', *The Atlanta Journal* 27/6/2002, p JM1.

[43] Palevitz B.A. 'Bt or not Bt ... Transgenic Corn vs. Monarch Butterflies' (1999) *The Scientist* 12:**13**:1.

[44]See discussion in, Cannon R.J.C, 'Bt Transgenic Crops: Risks and Benefits', (2000) *Integrated Pest Management Reviews* 3:**5**:151-173; Crecchio C, Stotzky G, 'Insecticidal Activity And Biodegradation Of The Toxin From Bacillus Thuringiensis Subsp. Kurstaki Bound To Humic Acids From Soil', (1998) *Soil Biology and Biochemistry,* 4:**30:**463-470.

battle over genetically modified crops. Both the popular and scientific press initially declared the monarch to be 'at risk' and 'under siege'.[45] However, other scientists responded that the study was inconclusive because it did not apply 'real world' conditions.[46] What is interesting is that, few attacked the validity of the data presented by Losey *et al*, as evidence of a hazard, what they did attack was their assertion that it was sufficient to be described as 'a risk'.[47]

In response to the Losey study, a variety of field studies were sponsored by the US Department of Agriculture (USDA).[48] These studies confirmed that Bt did present a potential hazard to the larvae. However, they concluded that it was much less sensitive to Bt in the field than in the laboratory and that the pollen drift for Bt corn was much smaller than previously reported.[49] In other words, the 'hazard' was confirmed but the 'risk' was not.

Following the second round of studies, debate concentrated on what the 'risk' actually was.[50] The USDA released a website declaring there to be 'negligible risk', and therefore the controversy 'resolved' by 'allowing science to guide decisions'.[51] Note however, that in doing so the USDA ensuring the continuation of commercial Bt crops, worth hundreds of millions of dollars to the US economy, because their continued registration was contingent on proof they posed no risk to

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[45] Carey J, 'Imperiled Monarchs Alter the Biotech Landscape', *Business Week*, 7/6/1999, p 36. Pew Initiative on Food and Biotechnology, *Genetically Engineered Corn and the Monarch Butterfly Controversy*, Report of the Pew Initiative on Food and Biotechnology, University of Richmond, Washington, 2002. p 3; Kleiner K, 'Monarchs Under Siege', (1999) *New Scientist* **162**: 4.

[46]Hansen L, Obrycki J, 'Non-target effects of Bt corn pollen on the Monarch butterfly (Lepidoptera: Danaidae)', Abstract D81, Annual Meeting, North Central Branch of the Entomological Society of America, 1999. Stanley-Horn D.E, 'Assessing The Impact Of Cry1Ab-Expressing Corn Pollen On Monarch Butterfly Larvae In Field Studies', (2001) *Proceedings of the National Academy of Sciences of the United States of America*, 21:**98**:1193.

[47] Palevitz B.A. 'Bt or not Bt ... Transgenic Corn vs. Monarch Butterflies' (1999) *The Scientist* 12:**13**:1.

[48] See Kaplan J, 'Bt Corn Not A Threat To Monarchs'(2002) *Agricultural Research*,2:**50:**16-19,

[49] *ibid.*

[50]Shadid A, 'Biotech Corn Cleared In 6 Tests Environmentalists Still See Possible Risk To Monarch Butterfly', *Boston Globe*, 11/9/ 2001 p A.3; Pollack A, 'New Research Fuels Debate Over Genetic Food Altering', *New York Times* 9/11/2001, p 25.

[51] The website is entitled '"Butterflies and Bt Corn: Allowing Science to Guide Decisions' and can be found at <www.ars.usda.gov/sites/monarch> (28/2/03).

the monarch.[52] It is also worth noting that the USDA undertakes considerable research into and commercialisation of, bio-pesticides such as Bt.[53]

The Significant Point. The position of the USDA is now generally accepted among agricultural scientists.[54] I use the term 'generally' because the USDA position does not reflect the opinion of *science per se*. Rather, some scientists still disagree with that conclusion and have undertaken studies of their own, finding that a 'significant' number of monarch larvae *are* affected by Bt pollen.[55] It is perhaps this question of 'significant' that lies at the heart of the monarch debate. For those who see the protection of the monarch as vital and the creature a symbol of 'nature', even a small affect may be 'significant' enough to describe the affect as 'risky' or 'high risk'. For others whose value judgment is set more towards agriculture, or the continuation of the science, the effect may be described as 'insignificant'.

What the monarch debate confirms is that science cannot provide *the* answer, because science has *many* answers, depending on who's doing the science. Moreover, it reveals that the divide between policy and science is a tenuous one, because raw figures needed to be interpreted by someone, and the process of

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[52]The commercial licence for Bt, granted by the US Environmental Protection Agency, was up for reconsideration only shortly after the Losey study. Anon., 'Bt Gets EPA Go-Ahead ... Again', (2001) *Progressive Farmer* **13**:116:7; Shadid A, 'Biotech Corn Cleared In 6 Tests Environmentalists Still See Possible Risk To Monarch Butterfly', *Boston Globe*, 11/9/ 2001. p A.3.

[53] For instance see Roe, *et al*, *Expression Of Cry3B Insecticidal Protein In Plants*, United States Patent, no. 6,517,856, 2003; Bulla , *Receptor for a Bacillus thuringiensis toxin*, United States Patent 6,455,266, 2002. see also Weller K, *Teamwork Boosts Biopesticides' Potential* Agricultural Research Report (June 1998), United States Department of Agriculture, 1998. pp 1-21.; Miller H, 'The Unexpected Arm of the Bio-Police' *Financial Times*, 21/12/1999, p 10; Sumerford D, 'US ARS: Securing Cotton Farmers' Bt Investment', *M2 Presswire*, 12/2/ 2001, p 1.

[54]Pew Initiative on Food and Biotechnology, *Genetically Engineered Corn and the Monarch Butterfly Controversy*, Report of the Pew Initiative on Food and Biotechnology, University of Richmond, Washington, 2002.

[55] One recent study concludes 'monarch larvae are affected by the Bt toxin Cry1A(b) …. when first- and early-second-instar larvae of the three non-target Lepidoptera were placed on host trees that were or were not sprayed with Bt, *significantly* [emphasis added] fewer caterpillars were alive on the Bt-treated trees after 5 days." Groot A.T, Dicke M, 'Insect-resistant transgenic plants in a multi-trophic context', (2002) *The Plant Journal* 4:**31**:406. see also Oberhauser K.S, *et al*, 'Temporal And Spatial Overlap Between Monarch Larvae And Corn Pollen', (2001) *Proceeds of the National Academy of Science* (US) 21:**98**:11913-11918.

interpretation involves some degree of subjectivity, implicit or explicit, realised or unrealised.

8.3.3 SUBJECTIVITY, SELF ASSESSMENT AND THE GTA

The GTA creates a system in which the licence applicant becomes the primary risk assessor, and the secondary risk manager [see 7.4]. If it can be accepted that risk assessment can be tendentiously oriented or subtly biased, then this presents somewhat of a conundrum for a regulatory oversight body, such as the OGTR, who relies on information from the very body it is licensing.

Whilst the Act does make stringent criminal provisions for the provision of false or misleading information,[56] it is unlikely that the level of value bias that may creep into self assessment is sufficient to amount to criminal *mens rea.*[57] Presenting one's own interpretation of data may be construed as partisan but it does not automatically render that interpretation false or misleading. There is then, a real potential for 'risk' to be constructed in a way that reflects what the proponent believes to be 'significant' rather than what the community does.

The regulatory alternative might have been to create a large scale regulator, with scientific laboratories, field technicians and full time scientific staff. In large countries or communities like the US or EU such organisations may be warranted. However, in a country the size of Australia, the regulatory burden presented by such a body is likely to be disproportionate to the amount of research undertaken. Moreover, given the technology is so novel and requires such a large amount of resources and expertise to understand and investigate, the task would have been rather arduous, requiring the agency to constantly keep abreast of the technology both technically and logistically.

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[56] s.192, GTA.

[57] Section 192 (GTA.) requires actual 'knowledge' that the information was false or misleading. The criminal element of knowledge requires a high standard of proof. *Thomas v The King* (1937) 59 CLR 279, *He Kaw Teh v The Queen* (1985) 157.CLR 523

A secondary option was to vest risk assessment powers in existing institutions such as the Commonwealth Scientific and Industrial Research Organisation (CSIRO).[58] However, given the CSIRO is actively involved in gene technology, it would likely have been perceived as purveying equally biased information, and unnecessarily drawn that organisation into determining policy questions.[59] Indeed, such a framework may have resulted in the CSIRO being forced to review its own licence applications, which would put it in a rather prone position. This is very much part of the dilemma that regulatory drafters face when deciding who should oversee risk analysis in a small country like Australia. Those with sufficient expertise to conduct assessments of the new technology are likely to come from the industry or research sector that is the subject of regulation [see 9.4].

To ensure the highest degree of expertise is applied to licence applications it is inevitable that we must turn to the experts. Yet these experts will interpret risk data in their own way, involving implicit, explicit, realised or unrealised subjectivity. This could have a major impact on the decision making process.[60] As such, it moves the overall regulatory process one step further away from Parliament and therefore one step farther away from the people. This marks part of the 'control paradox' referred to above, because the more in depth, hands on, control that is exercised, the greater the chance that societies fate could end up back in the hands of the technocrats. How the GTA is orientated to capacitate this problem is dealt with in the next chapter.

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[58] This was recommended by some Parliamentarians during debates. See Andren P, '*Gene Technology Bill* 2000 … Second Reading', 29/8/2000', *House Hansard*, p 19562; Secker, P '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19540.

[59] Indeed CSIRO was attacked by minor parties as being a gene technology proponent, and pushing the technology. See Brown B '*Gene Technology Bill* 2000 … In Committee', 4/12/2000, *Senate Hansard*, p 20604.

[60] see Lawson's article on the first licence grant application by the Regulator where he asserts that the "theory and practice of preparing the risk assessment conducted by he Regulator according to the Act's scheme is flawed … because the rhetoric of an objective and 'science based' risk assessment fails to account for content of the Regulator's value judgments". Lawson C 'Risk Assessment in the Regulation of Gene Technology' (1992) *Environmental and Planning Law Journal* **9**:211.

8.4 CONCLUSION

The point of this discussion is not to discredit the importance of risk assessment as a valuable tool of risk governance, but to reiterate McElveen and Amantea's argument 'assessors use *values* [emphasis added] which promote technology over equality or culture'.[61] If this can be accepted, then the basis for ranking scientific risks over ethical or social risks is less compelling, because they *are all* based on value judgments. Moreover, shattering the illusion that science – in application if not in discipline – is value free, allows non scientists to deliberate about risk, because the risk dilemma ceases to be the absolute realm of scientists and technocrats.

I would argue that the quest to establish whether GMOs cause physical harm to humans or the environment is merely part of an overarching ethical obligation to respect the dignity of those around us. It is, as recognised in the NHMRC *National Statement on Research Involving Humans* [see 5.1.1],[62] merely one of several principles which fall under the aegis of the obligation to 'do no harm'. Seeing the scientific quest as a subset of an overall ethos is even more apparent when we consider why environmental risk assessment is considered necessary. As Applegate emphasises,

> [t]he ethical and moral aspects of placing others at risk, of harming a natural patrimony, and of limiting the quality of life of future generations are by no means irrationalities that can be brushed off as nonobjective [sic] or mere opinion. They are the fundamental reasons for environmental protection in the first place, and they must be part of any credible environmental decision making process.[63]

This is not to say that ethics, economic and social hazards necessarily be conflated into the same assessment as 'scientific', physical hazards. I previously stressed the

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[61] McElveen J, Amantea C 'Risk Symposium: Legislating Risk Assessment' (1995) *University of Cincinnati Law Review* **63**:1553.

[62] National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans*, National Health and Medical Research Council, Canberra, 1999.

importance of using technology and science techniques to interpret, translate and capacitate novel technology. I also argued that risk assessment ensured a rigorous, systematic approach that could be subject to peer review and external evaluation. Indeed, the recognition that science is not value neutral seems to necessitate higher levels of scientific scrutiny and rigour, particularly in a scheme which utilises the proponent of technology as the risk assessor.

Therefore, there is a strong ground for examining the impacts of technology in relatively discrete disciplines. However, we must move past considering one discipline as more important than another, or raising it politically, institutionally and legally to a higher status. Rather it is the laws' role to deal with the risk dilemma in its entirety, to recognise the broader problems of the risk society for what they are, *broad* problems that 'are richer than that of experts' but still reflect 'legitimate concerns'.[64]

Risk assessment, is a regulatory tool, not a regulatory answer. It is an extremely important tool which I believe should remain part of the risk governance process. Hence, risk assessment can still be a tool used to distil (to the best of our ability) scientific risks from other risks, and consider them in an objective and transparent manner. However, there are two fundamental issues that must be recognised when using risk analysis as part of regulatory governance.

First, we must recognise and be honest about the value laden nature of that assessment, and build regulatory mechanisms to control it. There is an increasing recognition of this fact and risk assessment guidelines are beginning to be structured around ensuring that the interpretive bias required for risk assessment is recognised. The NHP Guidelines are particularly explicit on these matters, encouraging 'assessors, users, regulators and members of the public' to recognise

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[63] Applegate J.S, 'National Security And Environmental Protection: The Half-Full Glass', (1999) *Ecology Law Quarterly*, **26**:390.

[64] Slovic P, MacGregor D. M., *The social context of risk communication*, Decision Research Report No. 02-06, Oregon, 1994. p 9.

that 'risk assessment may not always provide a compelling or definitive outcome'.[65] The NHP Guidelines emphasise that,

> [t]he nature and use of default values and methods, assumptions and policy judgments in the risk assessment should be clearly identified. Conclusions drawn from the evidence should be separated from policy judgments … The summary should include a description of the overall strengths and limitations (including uncertainties) of the assessment and conclusions.[66]

The OGTR Risk Framework too, recognises the potential for uncertainty, and does permit the use of qualitative data where uncertainty arises. The Regulations also require that the risk assessor document any gaps in information and how 'big' that gap is (although this seems equivalent to asking how long a piece of string is). On the whole however, the OGTR Risk Framework seems much too emphatic about minimising any potential uncertainty or value judgments to play a part in the assessment. Of course as a guide to applicants, the OGTR Risk Framework is understandably oriented to encourage the fullest disclosure of information by those submitting data. Conversely, it may be important to emphasise the fallibility of risk assessment to those providing the data, and those interested parties who will seek to scrutinise it, so that a more objective picture of the risks can be obtained.

The second issue which is necessary to consider when utilising risk assessment is that we must not confuse *distilling* one discipline from another, with *eliminating* one discipline altogether. Recognition of the fact that all risks – physical, ethical or social – are merely subsets of an overall social problem, demands we afford them equally rigorous, systematic and transparent assessment systems. This is particularly important in a system where the scientific risks are, in part, determined by the licence applicant.

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[65] National Health Partnership, *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia, 2002 p 1.

[66] *ibid.* p xv.

The proponent of a technology is likely to see that technology as not only scientifically sound, but ethically acceptable and socially valuable. Such a regulatory approach would seem to necessitate a separate and rigorous system to objectively determine the ethical and social risks presented by an application. This requires building into risk governance, mechanisms that place 'non-physical' risks *on par* with physical ones. Some of the mechanisms to achieve this will be discussed in the latter half of this thesis.[67]

Approaching regulatory governance in a way that does not promote the ranking of one set of risks over another will be a challenge for the OGTR – a challenge which is made harder by the regulatory framework under which it operates. Yet, doing so would seem to be a regulatory imperative, one that is key to assuaging the concerns of the public in the blame society because the risk dilemma demands that full and complete control is exercised over all risks posed by technology, not just partial control over some of them. Moreover, making a clear regulatory statement that *all* risks will be considered legitimate and be subject to equivalent systems of review and scrutiny may go some way to diminishing the growing attitude that there is 'good science' and only 'bad policy'. If this is the case people may feel less compelled to 'cry wolf' and claim their concerns to be premised on 'science'.

Hence my argument is not for the diminution of risk assessment, nor even altering its process in any great way. Rather it is about creating equally relevant mechanisms for the assessment of the other risks (ethical, moral, social, legal, economic and so on) which are so predominant in the minds of the risk society. The risk society is not merely concerned with living, it is concerned with 'living well'. It is disingenuous to suggest that technological regulation is solely about avoiding immediate physical hazards. The whole point of this technological enterprise is to improve our standard of living and allow individuals to enjoy life. The very reason that government intervention is necessary is to ensure that the

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[67] I will discuss the importance of creating regulatory processes such as 'risk communication plans' at a later stage [see 17.2.217.2.4]. However these recommendations apply equally to ethics, so that processes are established to ensure a rigorous, systematic ethical 'assessment' of licence applications, akin to that set out under the NHMRC regime. [see Chalmers D, 'IECs And The Management Of Medical Research And Experimentation', (1995) *Australian Health Law Bulletin*, 5:**3**: 53-64] .

technology is used for those purposes. If regulation focuses only, or predominantly, upon physical health and safety, without regard to what individuals consider to be the important aspects of living, it is no different than a life support machine that maintains an otherwise dead patient.

9

RISK MANAGEMENT AND INDEPENDENCE

In coopting the risk analysis framework as the basis for the *Gene Technology Act* 2000 (Cth) (GTA/the Act) legislative drafters ensured that the GTA regime would:

- reflect 'best practice' for the assessment and management of risks;
- allow a more open 'peer reviewed' system ensuring scientific findings can be scrutinised;
- be flexible to incorporate change; and
- ensure the regulations adopted in Australia would not conflict with regulations elsewhere – thereby exposing the country to possible trade disputes.

Yet, as the previous chapter highlighted, in adopting this framework we must also realise that certain baggage is attached, in both the way this process operates, and the assumptions that underpin it. Since there is such a (justifiable) emphasis on truly understanding the scientific basis for risks, risk managers such as the Office of the Gene Technology Regulator (OGTR) must turn to scientific experts. Yet, because the interpretation of scientific data imports subjectivity and the construction of risk relies on value judgments, external agents are placed in a powerful position within the overall decision making process. Furthermore, the emphasis on the scientific basis for risk has created a culture that tends to rank

physical, quantifiable risks above all others. This means that the broad perception of risk held by the public can be undervalued, ignored or de-legitimised.

My criticisms of risk analysis – and in particular risk assessment – are not unique, they have been part of the debate over the applicability of that paradigm almost since its inception [see discussion at 8.2-8.3]. Indeed the process of criticism and peer review is very much part of the continued development of the risk analysis methodology. It is not unreasonable then, to expect that these weaknesses must have been considered in the drafting of the GTA. Therefore, the purpose of the following discussion is to examine how the 'baggage' of risk analysis has been dealt with within the risk governance framework of the GTA.

Risk Management. To follow on from the previous discussion I wish to examine the role of risk management in mitigating the problems created by the risk assessment process. Risk management is often held out to be means by which the efficacy of risk assessment is determined and the introduction of 'non scientific' concerns into the decision making process ensured.[1] It is during risk management that the actual decision is made as to what 'regulatory bracket' [see 6.2] an activity should be placed under and what conditions should be placed upon that activity. I do not wish to delve into the finite detail of risk management, but rather deal with how it has been utilised within the GTA to ensure that the process of delegation has not gone 'too far' outside Parliament's control.

The following section will discuss the Regulator's risk management role with particular emphasis on the issue of regulatory independence from external direction. I will argue that risk management is even less objective than risk assessment, and that independence does not *prima facie* lead to impartiality – in fact the opposite may be true. By having a single risk manager, making subjective decisions, based on potentially subjective risk assessment information,

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[1] "Risk management is the process of evaluating alternative actions, selecting options and implementing them in response to risk assessments. The decision making will incorporate scientific, technological and any other relevant considerations." Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001 p 12 "The focus of the elements of the risk management plan will be to ensure that potential risks to the environment and public health are not realised." *ibid*, p 15.

the system is prone to criticism for being undemocratic and susceptible to capture. Therefore, I shall argue that like risk assessment, risk management also contributes to the de-involvement of the public.

9.1 STANDARD SETTING

Under the Red Book paradigm, 'risk management' describes the formulation and maintenance of rules to manage the risks identified during risk assessment as well as the application of those rules (enforcement, monitoring).[2] The concepts however should not be dealt with in unison because each step differs both in practice, application and outcome. That is, rule making is irrelevant if rule application is lax. Similarly, rule application is irrelevant if no rules are set in the first place. For the purposes of the following discussion I wish to separate out, and deal specifically with, the formulation and maintenance of rules alone.

In order to avoid confusion I will refer to the formulation and maintenance of rules as 'standard setting'. This is particularly important because, even though the OGTR uses the term 'risk management' to describe the overall process of regulatory activity[3], the GTA only uses it within the context of a 'one off' plan, and then only with reference to licence dealings.[4] The phrase 'standard setting' is preferable to 'rule making' because 'rules' or 'laws' could be confused with laws binding the decision maker (the Regulator and the Ministerial Council) or the law maker (Parliament). Hence, 'standard' is intended to only canvas the requisite criterion expected of the *regulatee* and the way they undertake activities subject to the regime. Standard setting is taken then to mean the *decision* to apply thresholds to the activities of the regulatee.

Standards may be set to maximum permissible thresholds, such as limits on distance between crops or the maximum time for reporting. Conversely, standards may be set to minimum permissible thresholds, such as the level of training

[2] *ibid,* p 26.

[3] *ibid.*

[4] Part 5, Divisions 4,5. GTA.

required of employees or the condition of facilities. Standards may be active, such as the need to self-police, or passive, such as refraining to undertake an activity. They may also be utilised in a narrow sense, to apply to activities or behaviour of an individual body or they may be denoted in a broad sense to cover a class of activities or modes of behaviour. Whereas the decision as to 'where' to set the threshold is probably the most significant, the question as to how broad to set it is also of some importance. A narrow standard will entail a focused interference with a person or body. On the other hand, a broad standard may either unduly affect some licensees (such as start-ups) or be too lax in respect of others.

9.2 INDEPENDENT STANDARD SETTING

The independence of the Regulator to make decisions and set standards was considered from the earliest stages to be a key component of an effective regulatory system. The Government told the Senate that there had been an 'overwhelming' view from all groups that the [Regulator's] office must be independent.[5] This was supported by a large number of submissions to both house inquiries.[6] For instance, the Australian Food and Grocery Council noted that:

> to be effective, the office must be independent …the operational framework must ensure that the office is independent of commercial, political and sectoral influence.[7]

Senator Foreshaw argued that the gravity of responsibility upon the Regulator was such that misjudgements would have 'major health, safety and environmental ramifications'.[8] He emphasised that, in setting standards, the Regulator would

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[5] Campbell I, Gene Technology (Consequential Amendments) Bill 2000 …Second Reading Date', *Senate Hansard*, 30/8/2000, p 16961.

[6] Submissions No.85, p 13 (ACF GeneEthics Network); No.70, p.1 (Professor Gibbs); No.32, p.9 (Avcare Ltd); No.71, p.9 (AFGC); No.110, p.2 (South Australian Government); No.70, p.1 (Professor Gibbs); to the Senate Committee
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[7] *Community Affairs References Committee Hansard*, 25/8/2000, p 399.

[8] Forshaw M, '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 6/11/ 2000, p 19192.

have to consider 'conflicting reports and evidence based on scientific conclusions that are changing rapidly.[9] Thus, there was a recognition from the outset that scientific evidence could potentially be flawed.

Independence From Government. What is perhaps most interesting about the debate over the need for regulatory independence, is not the emphasis on mitigating stakeholder and community influence, but limiting governmental influence.[10] Moreover, much of that emphasis came from within Government itself.[11] Government was seen as particularly susceptible to lobbying and shifting political environments. Hence, both sides of the debate were concerned that any pressure brought to bear upon Government by the opposing constituency could potentially percolate into the Office of the Gene Technology Regulator (OGTR). [12] Moreover, because Government had taken an active involvement in the promotion of gene technology – by funding research; providing incentives to private industry; and releasing a national strategy to ensure it's ongoing development [see 14.3.2] – there was a recognition that any regulatory agency not completely independent from the executive may appear biased.[13]

The Government therefore maintained from the outset that the OGTR should be 'highly independent … and in whom, at the end of the day, the Australian community can have faith'.[14] There was bipartisan support for this notion, with the Opposition emphasising that regulatory independence was 'probably the most important factor in establishing a regulatory system that will inspire confidence amongst the Australian public'. [15]

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[9] *ibid.*

[10] *ibid.*

[11] *ibid.*

[12] *Community Affairs References Committee Hansard*, 25.8.00, p.399.

[13] Forshaw M, '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 6/11/ 2000, p 19192.

[14] Tambling G, '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 8/11/2000, p 19369.

[15] Forshaw M, '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 6/11/ 2000, p 19192.

9.2.1 MAINTAINING INDEPENDENCE

Whereas both sides of the political divide agreed the OGTR should be independent, they disagreed about how independence was to be ensured. The Opposition argued that the potentially massive and conflicting risk assessment information would render standard setting too subjective and too dangerous to be dealt with by a single individual.[16] In light of these factors it was argued that there should be not one but three regulators to ensure that standards were applied with independence objectivity and due significance. The majority of the Senate Community Affairs References Committee, charged with reviewing the Gene Technology Bill, (the Senate committee) echoed this view stating:

> the current proposal the final decision rests with one person is of concern in terms of the level of responsibility and pressure this one person will have and perceptions that one person may not be able to resist pressure from outside influences, industry or Government. This being the case the Committee recommends that the independence and impartiality of the office will be enhanced by the establishment of the Regulator as a statutory authority, where a board of three people will take ultimate responsibility for decision-making.[17]

The suggestion that a statutory authority was the most effective way of regulating was dismissed by the Government, who contended that it was too costly and would introduce bureaucracy and anonymity into regulation.[18] The Interim Office of the Gene Technology Regulator (Interim OGTR) supported the Government's stance. It asserted that a single Regulator was in keeping with international best practice. A sole Regulator, argued the Interim OGTR, was the most appropriate way to ensure proper transparent and independent standard setting.[19]

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[16] *ibid.*

[17] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, 2000 para 4.20.

[18] Tambling G, '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 8/11/2000, p 19369.

[19] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, 2000, para 5.9.

Emphasising the Government's stance, the dissenting members of the Senate committee (representing Government Senators) stated they were '*entirely opposed*' to the OGTR being overseen by more than one Regulator. Establishing the office as a statutory authority, they argued, would increase the cost of regulation by $500,000 a year.[20] They put that there was no way to justify the 'unquantifiable gain' that three regulators would bring as independence could be ensured through legislative provisions, not by adding more people to the decision making process.[21] I would submit this argument is rather tenuous, because independence is *inherently* unquantifiable, whether there be one or three Regulators. However, it does seem an acceptable inference that one individual may be more susceptible to committing mistakes or to external influence than three. Furthermore, the cost suggested seems rather small in relation to Commonwealth funding to gene technology, being less than one percent (0.0022%) of the annual $250 million dedicated to gene technology research.[22] As one Senator noted:

> If the OGTR were given half the amount of money that the Government spent on the one-off GST advertising campaign, we could run a three-person board for over 100 years. To us that sounds like extremely good value in terms of public confidence and good public policy.[23]

The Diversity Principle in Law. Diversity of decision making is a principle which lies at the core of democracy and our modern political system. The law has traditionally been wary of vesting decision making powers to a single decision maker, particularly where the outcome of that decision will affect a large group or indeed the whole of society. Most certainly this principle underlies monopoly and the corporations laws prohibiting the sole directorship of public corporations.[24]

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[20] *ibid.* p 182.

[21] *ibid.*

[22] Minchin N, *Funding for Biotechnology Strategy*, Media Release (B99/112), Commonwealth of Australia, Canberra, 1999.

[23] Forshaw M, '*Gene Technology Bill* 2000 G … Second Reading', *Senate Hansard*, 6/11/ 2000, p19192.

[24] For instance public companies must have at least three directors. *Corporations Law*, ss 221(1), (2). It is also evidenced in the Government's intervention in corporate monopolies see, Senate Standing Committee on

Whilst group decision making can prove fallible and decrease efficiency, these shortcomings have generally been accepted as a lesser evil to all power being placed in an individual.

There would seem no reason why the principle of diversity in decision making should not be extended to the public sector. Indeed, where the decision will have such a profound and widespread political and economic impact there would seem a necessity to import the principle. It would lessen the dilemma of 'who makes the decision' about what risk is by providing greater objectivity to the determination.

Nevertheless, the concept of a statutory authority was not incorporated into the final Act. Instead impartiality was to be ensured by various statutory devices within the GTA itself.

9.2.2 INDEPENDENCE PROVISIONS

The primary guarantee of regulatory independence is an express provision within the Act declaring the Regulator to be independent from external influence in the course of standard setting. Section 30 of the GTA states:

> [T]he Regulator is not subject to direction from anyone in relation to: whether or not a particular application for a GMO [Genetically Modified Organism] licence is issued or refused; or the conditions to which a particular GMO licence is subject. [25]

Independence is also intended to be assured via the appointment process. The Regulator may only be appointed if it can be shown that person has no commercial or pecuniary interest in, or has been employed in the last two years by, a corporation which produces genetic technologies.[26] Furthermore, the Regulator must disclose all interests, economic or otherwise, that could 'conflict

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Legal and Constitutional Affairs, *Mergers, Monopolies and Acquisitions: Adequacy of Existing Legislative Controls*, Commonwealth of Australia (AGPS), Canberra, 1991.

[25] s. 30, GTA.

[26] ss.118(5),118(6) GTA.

with the proper performance of the Regulator's functions'.[27] The Regulator may also be dismissed if a majority of jurisdictions and the Governor General agree that she or he has 'misbehaved'.[28]

Benefits of Independence. The GTA creates a single Regulator who will generally be immune from commercial, administrative or executive control. This level of independence is seen by each constituency as beneficial, because it diminishes the degree of influence the opposing constituency may make on regulatory outcomes. It is also seen as beneficial by the Government, because it places regulatory decisions at arms length. This is attractive, both because it distances government from politically sensitive outcomes and also because it ensures the regulator appears impartial and thus is trusted by the community. Regulatory independence ensures that the licensing process is undertaken in an efficient and streamlined manner by avoiding administrative 'red tape'.

Disadvantages of Independence. Whilst there are clear advantages to maintaining independence, it must be simultaneously accepted that, in creating a single, independent regulator, the Parliament placed the process of exercising sovereign power outside its direct control. Moreover, section 30 of the GTA (the independence provisions) relate specifically to decisions about individual licence applications. Individual licenses involve the highest degree of regulatory intervention – being the narrowest form of standard. Licence decisions are also the most reliant on data and opinion from technocratic agents. Thus, where there is the greatest regulatory intervention and when it is most involved in corporate activity, it is not Parliament making the decisions but a single agent in collaboration with the regulatee. As will be established in the next section it also leaves the Regulator in a position where some degree of subjectivity will naturally creep into the decision making process.

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[27] s.120, GTA. Failure to disclose conflicts of interest will result in the dismissal of the Regulator. [s. 119(3), GTA.]

[28] s. 119(1), GTA.

9.3 THE SUBJECTIVITY OF STANDARD SETTING

If risk assessment is capable of subjectivity, risk management is particularly so, especially in relation to standard setting. Hawkings[29] argues that in setting standards, a decision maker may wittingly or unwittingly become concerned not only the attenuation of public risk, but the economic and social impacts upon the regulatee or the risk management decision. Sunstein[30] further posits that concerns about being overly stringent or overly severe play a large part in regulatory decisions. Indeed, there will always be a certain political reluctance to over restrain economically productive behaviour.[31] Hence risk managers can knowingly or unknowingly be influence by personal values. Simultaneously, the very philosophy of standard setting can be seen as value oriented. Standard setting, as a subset of the regulatory process is ultimately designed to give affected parties a chance to exert an influence over activities, which they would usually be unable to control. Thus, it is, in principle, about ensuring the just application of personal and public rights, fairness, equity and justice.

Given these value judgments will be a part of standard setting, Hawkings describes the process as 'moral' because it centres around what is 'just' and 'fair' on both those that the regulation seeks to protect and those which it seeks to regulate. I will avoid the use of the term 'moral', because it has too many connotations, particularly given the previous discussion on risk. However, it is worth reflecting that, given sufficient legislative ambit, a regulator may set standards in deference to what they believe is the acceptable degree of infringement upon the personal and property rights of the regulatee and the public.

In accepting that standard setting will incorporate subjectivity and value judgments, two issues arise. The first is that, a regulator may make unfair decisions or ones that do not exercise the degree of control necessitated by the risk dilemma. The second is that the regulator may arrive at decisions that appear fair and balanced or seem to exercise sufficient control but are contrary to the

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[29] Hawkings K, *Environment and Enforcement*, Clarendon Press, Oxford, 1984, chpt 9.

[30] Sunstein C, 'Paradoxes of the Regulatory State' (1990) *University of Chicago Law Review* **57**:407-441

[31] Hawkings K, *Environment and Enforcement*, Clarendon Press, Oxford, 1984, chpt 9.

intention of the wishes of Parliament. In both cases the issue is one of unfettered discretion. The question is how to narrow the ambit of that discretion without creating an overly rigid regime which is incapable of capacitating emerging knowledge and novel technologies.

9.4 THE THREAT OF CAPTURE.

It was noted above that standard setting often imports value judgments about what is politically, economically, or socially 'fair' or 'just'. Thus, it was suggested that a large degree of independence, can lead to outcomes which are potentially contrary to the policy of the enacting or existing Parliament. The other potential downfall of independence is that it leaves the decision maker prone to 'capture' by external parties or policies.

Capture theory focuses on the interplay between the agency and the 'agent' or regulator and regulatee. Theories on capture have dominated regulatory dialogue since the 1950's and have been based on the assumption that a regulatory agency will generally act to ensure stability and self-preservation.[32] This, regulatory theorists argue, will occur for two reasons.

Capture through Value Judgments. First, because the agency will be reluctant to inhibit economically beneficial activity. This was discussed above in relation to the subjectivity of standard setting [see 9.3] Overly prescriptive standard setting is likely to be seen as inhibiting the market and will attract pressure both from industry and from Government. Regulators are not immune to such pressure.[33]

Capture by Cooperation. The second source of capture is the limited resources provided to regulatory agencies which oblige them to elicit the participation of the regulatee in the overall process of management.[34] Constant regulatory oversight

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[32] see Bernstein M, Marver H, *Regulating Business By Independent Commission*, Princeton University Press, Princeton, 1955, p 83; Selznick P, *TVA and the grass roots. A study in the sociology of formal organisation*, Harper and Row, New York 1966.

[33] *ibid.*

[34] *ibid.*

is in reality impossible, at least where there are a large body of regulatees. Hence, a regulator must create an environment where regulatees comply in the absence of direct policing.[35] It is important in such circumstances for a regulator to create an environment where regulatees are responsible, willing to participate and to disclose relevant information without coercion. As such, a basic level of trust between regulator and regulatee must be established and the regulatory agency must foster a 'working relationship' with industry. The current Regulator notes:

> we have worked really hard to build a relationship between [the OGTR and] … people under the office and I think this has, so far, worked really well ...[36]

If the agency is too harsh in the standards it implements or the way it polices that body the regulatee is likely to distance themselves from the regulator and be reluctant to participate in the regulatory relationship.[37] A bad perception of the regulatory process may alienate other regulatees from the regulator.[38] Regulatory agencies are very aware of the need to avoid estranging the regulated industry and thus actively attempt to foster relationships with the industry. Indeed, the reliance placed on the licensee for quality risk data is a potential area where it will be important to create a positive regulatory relationship [see 7.4]. It is both the need both maintain this relationship and the relationship itself which underpin capture theory.

A Subtle Shift. The conscious effort to 'maintain' good relations clearly may lead to partiality towards the regulatee. However the relationship itself may also lead, over time, to 'subtle' shifts in regulatory practice where the 'mores, attitudes and thinking of those regulated come to prevail in the approach and thinking of many

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[35] Kinsey K 'Deterrence And Alienation Effects On IRS Enforcement: An Analysis Of Survey Data', in Slemrod J, *Why People Pay Taxes: Tax Compliance and Enforcement, University of Michigan Press*, Michigan, 1992, pp 259-285.

[36] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

[37] Makkai & Braithwaite's studies into nursing home regulation revealed that harsh regulation can lead to a defiance and evasion by the regulatee Makai T, Braithwaite J 'The Dialectics of Corporate Deterrence' (1994) *Journal of Research in Crime and Delinquency* **31**: 347-243.

[38] For instance Kinsey's studies into willingness of individuals being audited to comply in the audit process decreased significantly when they heard that the auditors were harsh and unfair. See Kinsey *op cit*, 35.

regulatory officials.'[39] Here the issue is not so much direct bias as it is a sympathy with the regulatee which the Regulator may develop by virtue of the interaction between the two groups.

Capture and Standard Setting. Generally, the degree of capture relevant to the setting of standards can be expected to be minimal. Capture theory is most relevant to enforcement and compliance of those standards, an issue largely outside the scope of this thesis. Standards are unlikely to be so affected by the agent because they are the public face of regulatory activity by the agency. The same drive for self-preservation that is the basis for capture is likely to have an equal effect to the opposite. That is, the agency will be concerned that the citizen and interest groups perceive it to be applying strict standards. This is not to say that standard setting is incapable of being captured given the right circumstances or the right regulatory architecture. A system which is engineered to rely or relate too closely to the regulatee could potentially lead to standards being set at levels which are sympathetic to the regulatee and hence are imbalanced, value based, or contrary to parliamentary policy.

Within the GTA architecture three principle sources could be pointed to as having the potential for inducing a capture into standard setting. These are: the appointment of the Regulator; cost recovery; and public image.

9.4.1 APPOINTMENT

Bernstein has suggested capture often occurred because of what has come to be known as the 'revolving door' theory of regulation.[40] Industry executives tend to take up powerful positions in regulatory agencies because of their proximity, prominence and expertise to the subject matter.[41] The opposite is also true, people in power in regulatory agencies often look to move to the private sector eventually as it is a source of more lucrative income.[42] This encourages sympathy from

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[39] Bernstein M, Marver H, *op cit* 32.

[40] *ibid*, p 185. see also Gormley W, 'A Test Of The "Revolving Door" Hypothesis At The FCC', (1979) *American Journal of Political Science*, **23**:665; Roberts J.S, 'The "Revolving Door": Issues Related to the Hiring of Former Federal Government Employees', (1992) *Alabama Law Review* , **43**:343-344.

[41] see Roberts, *ibid.*

[42] *ibid.*

regulators because either they have been on the 'receiving end' of regulation or they wish to court the industry who is on the 'receiving end' of their regulation.

The Gene Technology Revolving Door. The narrow field of gene technology is no exception to the 'revolving door'. With only a relatively small field of local experts having both sufficient scientific and regulatory expertise in gene technology, the chances of capture are increased. From this perspective at least there is a degree of inevitability to capture because to there will always be potential for the Regulator's prior experience, background and training to influence decisions. It would be entirely unrealistic for legislation to expect the decision maker to have expertise in gene technology while simultaneously expecting complete impartiality from that same body. However, if impartiality is to be valued, legislation should provide mechanisms to limit the degree of capture.

It was noted above [see 4.3, 9.2.1] that the appointment of the Regulator is intended to ensure independence by requiring disclosure of all pecuniary or other interests in gene technology. Most importantly, the Act requires that the a candidate to the role of Regulator disclose all pecuniary interests which could conflict with the proper performance of regulatory functions.[43] Whilst there is no requirement to disclose previous pecuniary interests, a candidate cannot be appointed to the position of Regulator, if either they have been employed in the last two years by, or have a current pecuniary interest in a company 'whose primary commercial activity relates directly to the development and implementation of gene technologies'.[44]

Is Minimising Capture Possible Through Appointment? There was a clear intention by the Parliament to ensure that biased and capture were minimised by ensuring that no direct conflict of interest exists in the role of the Regulator. However, in a great number of cases there will be uncertainty as to what constitutes activities 'directly related to the development and implementation of genetic technologies'.[45] On its face, such a restriction would seem orientated

[43] s.120, GTA.

[44] sub.118(6), GTA.

[45] subs.118(5), 118(6), GTA.

towards prohibiting the appointment of ex-members of corporations that are involved in the scientific research and development of Genetically Modified Organisms (GMOs). This seems a rather narrow approach to what could potentially bias an appointee. If the provision only related to corporate interests it would permit the appointment of individuals who are members of political or non-profit organisations that support or promotes the development and implementation of genetic technologies.

Other roles, which may have biased a regulator, may include membership, or management of, any group opposed to gene technology, or in a broader sense, an environmental group, that has campaigned against GMOs as part of their overall activities. A solicitor who solely represented corporate gene technology interests may also be biased towards the industry, although it would be questionable as to whether this fit within the definition of conflict. In all these cases the history of such an applicant could be said to sufficiently impact on individual decisions in such a way that potentially bias certain applicants. Yet it is arguable that the applicant or Regulator would not even be required to declare such interests.

Conflicts of Interest. Section 120 of the Act, which requires that the Regulator disclose such interests that would *' conflict with the proper performance of the Regulator's functions'*. The intention here is directed at overt bias not the 'subtle mores' of sympathy associated with capture. The Act does not clarify the measure of interest or bias which would constitute conflict with 'proper performance'. This instead will be a political question which will evidence itself in practice. It did not take long for this issue to gain prominence with the appointment of the first Regulator coming under fire from some sectors.

The Debate Over the Current Appointment. The appointment of the current Regulator was heavily criticised by the anti-industry constituency because of she 'long promoted gene technology'.[46] Since 1984 she has been variously employed to:

- commercialise gene technology based ventures for private companies;

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[46] Anon., 'Federal Government Under Fire for Gene Job' *ABC Rural News,* Transcript, 1/10/01 <http://www.abc.net.au/rural/news/stories/s379498.htm> (12/6/02).

- establish and encourage of gene technology based industry within Western Australia;
- improve Western Australia's capacity to foster gene technology start-ups and;
- increase investment in Western Australia research and integrate and expand research and development of science and technology across the whole of Government.[47]

The criticisms of the current Regulator's appointment however, failed to recognise that she had qualifications as a marine biologist with a doctorate investigating regeneration of coral and had as part of her various employment portfolios included briefing clients on bioethical and regulatory issues and the development of environmental management and renewable energy.[48]

The Minister for Health Dr Wooldridge defended the Regulator's appointment arguing that :

> I think you want someone who understands it, and someone who's not going to take a head-in-the-sand view … there are some people who hold extreme views in this area. I don't take them very seriously. They represent a very small minority of the Australian viewpoint.[49]

The Ministers point was clear, so long as the Regulator was required to have an expertise in gene technology, her or his appointment would attract criticism because of the history of that very expertise. So, in a way, a degree of capture, or at least perceived capture, is inevitable – especially where the office to which that

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[47] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.* Wooldridge M. 'New Gene Technology Regulator to Take Up Position In December', Media Release (MW98/01) Department of Health and Aged Care, Canbera, 2001.

[48] *ibid.*

[49] Ed., 'Minister Defends Meek Appointment' *ABC Rural News*, 1/10/01, <http://www.abc.net.au/rural/news/stories/s379511.htm> (10/12/02). As an interesting historical note Dr Wooldridge would later be placed under investigation for awarding $5million in Commonwealth funding to a body which he was employed by subsequent to his tenure in his Governmental office – a rather overt example of the revolving door theory in action. Ed., 'Health Programs to Get Diverted $5m' *The Australian*, 11/3/2002.

person is appointed, is highly independent. The issue is whether this inevitability will be proactively resisted or subtly utilised by the appointing Government.

Utilising Capture. The use of the appointment process to effect policy, where the Government might not ordinarily have had political sway – or where the Government does not wish to appear to have political sway – is not a novel concept. In Australia, judges of both federal and state jurisdictions are appointed by the Government of the day.[50] While there is a requirement for consultation this is quite formalised and it has been suggested that in some instances the Cabinet has ignored completely the advice and elected its own preference to the position.[51] This system has often been pointed to as affecting the relative activism or conservatism of the High Court.[52] Literalist judges tend to have been appointed by conservative governments while activists have been appointed by labour governments and the appointment process has been seen by some as a manner in which the executive can influence the direction of the law.[53]

Capture then can be used as a political tool, particularly where it is combined with independence. Unrestricted, a Regulator can act in a biased manner simply by virtue of their allegiances, sympathies or value judgments. Government is not ignorant of this, so the question lies as to whether capture is offset by institutional mechanisms or subtly utilised to promote one view-point or the other, whilst appearing distanced from the decision making process.

9.4.2 COST RECOVERY

In the originally envisioned framework the Commonwealth promised an initial $7.6 million to establish the Office of the Gene Technology Regulator (OGTR),

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[50] *A-G (NSW) v Quin* (1990) 170 CLR 1, per, Brennan J at 33; see Chappell D, *Judicial Responsibility: A Review Of The Selection Process For Australian Judges*, Australian National Report for the Eleventh International Congress of Comparative Law, Caracas, 1982.

[51] Kirby M *Legal Institutions In Transition Modes Of Appointment And Training Of Judges - A Common Law Perspective,* CMG Seminar Paper (Presented 8 June 1999), Belfast, Northern Ireland, 1999. <http://www.hcourt.gov.au/speeches/kirbyj/kirbyj_judicial2.htm> (8/12/02).

[52] *ibid.*

[53] Derkley K, 'The Future Of The High Court Is In Howard's Hands' (1997) *Australian Lawyer* 7:**32**:8.

after which time the agency was to be self-funding.[54] That is, it was to recover its costs from licence and administrative fees.

The concept of full cost recovery drew criticism from several sectors for potentially rendering the Regulator 'captive of the industry.[55] This it was suggested would reduce the public's trust in the capabilities of the Regulator to be impartial an unbiased. [56] The Consumer Food Network of the Consumers' Federation of Australia submitted to the Senate inquiry that 'we oppose 100% cost recovery from industry for the running costs of the Regulator. This could lead to perceptions of industry capture of the Regulator'.[57] The Australian Food and Grocery Council went further and alleged that full cost recovery would lead to 'criticism of collusion, with the [Regulator] particularly exposed as being unduly influenced by industry through reliance on funding from granting permission to develop GMOs.'[58]

The Opposition argued that,

> In practical terms, the [Regulator] will be required to approve a sufficient number of GMO licences to obtain the annual licence fees to continue to operate the day-to-day activities of the office. Further, and paradoxically, the [Regulator] will only be able to obtain funds …by approving enough dealings with the GMOs to raise the money needed. The independence and impartiality of the [Regulator] must not be compromised by this full cost-recovery model or by the delegatory [sic] powers of the [Regulator].[59]

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[54] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra, p 2.

[55] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, para 4.13.

[56] Submissions No.32, p.9 (Avcare Ltd); No.71, p.9 (AFGC) to the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[57] Submission No.50, p.5 (Consumer Food Network) to the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[58] Submissions No.71, p.10 (AFGC), No.32, p.9 (Avcare Ltd) to the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[59] Sidebottom S, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19536.

The Government was largely silent on the issue, with Governmental Senators stating only 'while Government Senators recognise that there is a degree of anxiety about the issue of cost recovery, the policy is 100 per cent cost recovery'.[60] The Government charged a corporate auditor, KPMG consulting, with investigating the impacts of complete cost recovery and alternative options for regulatory funding.

After reviewing the impacts of the initial funding plan, KPMG concluded that, 'there is a degree of fragility in attempting to fully recover all the costs of the OGTR'. [61] The Government chose to extend funding of the scheme for an extra year. However the KPMG review focused almost entirely on the problems faced by the *industry* and research and development should full cost recovery be implemented immediately. It did not investigate the potential for regulatory capture should the Regulator be made reliant upon fees from the industry.

KPMG did conclude, '[t]hat is not to say that such a regime could not be introduced'.[62] The Commonwealth is set to review the cost recovery process. The review is intended to take into account consultations with the gene technology industry, that is licensees and the Productivity Commission Inquiry into Cost Recovery by Commonwealth Regulatory, Administrative and Information Agencies.[63] Again, the focus of cost recovery seems to be on its impact on industry rather than on the efficacy of the practice in relation to regulatory decisions.

In the interim the Regulator will continue to source a proportion of its funds via licence applications. The *Gene Technology (Licence Charges) Act* 2000 (Cth)[64]

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[60] Bartlett A, Committees Community Affairs Legislation Committee Report, Senate Hansard, 2/11/2000, p19025.

[61] KPMG Consulting, *A Model for Cost-Recovery in the Office Of The Gene Technology Regulator*, Report to the Interim Office of the Gene Technology Regulator, Commonwealth of Australia (AGPS) Canberra, part II, p 19.

[62] *ibid*, part I, p 4.

[63] Office of the Gene Technology Regulator, *Questions and Answers on the Gene Technology Act 2000*, Office of the Gene Technology Regulator, Canberra, 2002, p 15.

[64] The Australian constitution requires that matters of taxation must be dealt with solely by a specific taxation Act. [s. 55, *Constitution of Australia* 1900].

prescribes that licence holders will be liable for continuing annual charges.[65] Like the GTA, the Licence Charges Act establishes delegated regulations, which will allow the Regulator to elaborate and update the specific charges.[66] Other one-off costs may also be levied under the Licence Charges Act, such as charges for certification or accreditation.[67]

9.4.3 CAPTURE AND PUBLIC IMAGE.

Regulatory agencies are in principle represented as politically neutral and disinterested in their public image. Yet capture theory suggests the opposite and as Selznic indicates factors such as 'prestige and survival' are 'real factors' in decisions made by an agency.[68] Regulatory agencies are sensitive to the political environment (they are a public bureaucracy) between industry and consumer or environmental groups. Indeed they are capable of sympathy towards one constituency more than another because inevitably regulators will have come from one constituency or another.

The threat that independence poses in such an environment is that sympathy will translate into unbalanced standards being created and applied, but will this always be the case? As stated previously, standards are very much the public face of regulatory activity. The very tenet of regulatory capture that dictates that regulatory agencies are not immune to public perceptions creates pressure in the opposite direction. In other words, the need to foster public trust will ensure that balance shifts back towards stringent intervention. The more aware the public become of the potential for coercion or sympathy, the more likely the regulator is to feel pressure to distance themselves from the regulatee.

Hawkings argues that the economic rationale that dictates that a regulatory agency can only be as successful as the capital it has is too narrow.[69] Regulatory

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[65] s.4, *Gene Technology (Licence Charges) Act* 2000. (Cth) [herein Licence Charges Act]

[66] s.5, *Licence Charges* Act.

[67] Prt. 9, Div.3, GTA.

[68] *op cit* 32, p 65.

[69] Hawkings, *op cit 31.*

decisions are not driven simply by economics, they are undertaken in a political, social and moral environment. Public appearances, political and economic repercussions are then equally factored into decisions by a regulator. A regulator who has been targeted by non-industry groups as being biased is more likely to act in a manner which assures the community that the agency is credible and effective. Indeed those groups will likely actively monitor the Activities of the Regulator and publicise any perceived breach. This is not to suggest that legislation may not create an avenue towards capture. It does however indicate that, given sufficient visibility and transparency, the degree of that capture may be minimised. Hence monitoring, review and public involvement are important aspects of any regime which purports to be impartial and independent (these will be discussed in chapter 18).

9.5 CONCLUSION

The issue of independence comes to dominate regulatory discussion where Government ceases to be an impartial arbiter of the risks and benefits of technology and begins to actively promote it. In that instance its obligation to control the technology and its interest in promoting the technology can overlap and place it appears to become a technocratic agent itself. Hence impartiality became a major issue in debates over how the GTA regime would operate and how the standards under it would be set.

The solution to the conflicting governmental roles adopted by the Parliament, was to create a Regulator that was 'independent' from Government and industry. This it was believed would provide a clear demarcation between the two roles Government has adopted. However the debate concentrated so heavily on ensuring impartiality, through the device of independence, the negative aspects of independence were often overlooked, or underrated. Rather, there was a tendency to view independence as a catchall device to ensure standards would be set fairly and without bias or sectorial influence.

From the above discussion it is clear that independent standard setting is not the only solution to ensuring an impartial and objective decision-making process.

Instead, independence can render the decision making process susceptible to bias, subjectivity and imbalance, particularly where there is only one person making those decisions. Thus, we must question whether it is the most effective option for solving the risk dilemma, because that dilemma is caused by the subjectivity of risk and questions as who should make the decision as well as how to avoid bias and imbalance.

Unfettered independence can then compound the risk dilemma. Moreover, it excises the standard setting process from direct Parliamentary control. It places politically sensitive decisions at arms length from Government and draws criticism away from the executive. Government does not have to make the hard decisions nor defend them. Independence reduces the amount of public influence over public risk decision-making, because it moves the decision-making process one step further from the constitutional restrictions on Parliamentary sovereignty.

Independence also has disadvantages for the Government, because the separation between Government and Regulatory agency may result in outcomes Parliament never intended. Should such results be considered unfair or unbalanced, Government may ultimately be seen as responsible for creating a scheme which is flawed or which allows for flawed results. So true independence may not always ensure impartiality. Independence can in fact undermine impartiality where external influences are too strong or internal biases affect the outcome.

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RISK, STANDARDS AND PARLIAMENTARY INFLUENCE

Regulatory standards are by far the most public and perpetual record of legislative behaviour. They are the public face of regulatory relations between licensee and regulator, for which the Government is ultimately responsible. They manifest the policy behind regulation and the degree to which a legislative system will intervene in private activities. They provide a degree of legitimacy and certainty to legislation, by placing those affected by legislation on notice of the limits on their activities. Similarly they provide a degree of certainty to those that legislation is intended to protect, that certain activities will be monitored and controlled. In both cases standards act as a basis against which perceptions of excessively or insufficiently stringent intervention may draw criticism.

Standards are then open to a large degree of scrutiny from private and public institutions and hence are politically sensitive decisions. Therefore, whereas independence to set these standards is an attractive option in some aspects, it can be counterproductive in others. Should the government stand too far outside of the decision making process, it may ultimately be blamed for enacting – or failing to temper – regulation which is either too stringent, too lax, or indeed too ineffective by one constituency or the other. Moreover, should it remove itself from the regulatory process altogether the legislature can appear not to be in ultimate control of technology and the risks that it poses.

Limiting Discretion. The immediate solution to unfettered discretion would be to constrain the independence of the agency or direct the manner of standard setting. Clearly this would undermine the arguments I have made previously about the need to ensure dynamic legislation. Moreover constraining regulatory independence would be contrary to the policy set out under Section 30 of the *Gene Technology Act* 2000 (Cth) (GTA/the Act) and would attract criticism from all sectors.[1]

Section 30 was discussed above [see 9.2.1] and basically states that the Regulator cannot be dictated to, by *anyone* in setting standards under the GTA regime. However, whilst Section 30 does minimise influence on standard setting by the Gene Technology Regulator (the Regulator) it does not totally eradicate it. Section 30 deals with *specific* direction with respect to *individual* licenses or narrow standards but not broad or generalist direction.[2] So in fact while independence is central to the regime, the GTA does not provide for absolute independence. Instead it creates or allows for the creation of superior generalist standards, which bind even the Regulator. The following section will examine how the Act limits the standard setting process so as to guide risk management towards an outcome that is in keeping with parliamentary intention.

Sources Of Discretionary Fetter. The GTA constrains unfettered discretion through five principles sources. These are,

- the objects of the Act,
- obligations set out from within the Act,
- binding codes (policy principles),

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[1] s.30 GTA states "… the Regulator is not subject to direction from anyone in relation to: whether or not a particular application for a GMO licence is issued or refused; or the conditions to which a particular GMO licence is subject."

[2] This framework is consistent with existing Commonwealth regulation of health and safety. For instance therapeutic goods regime empowers the Minister to create general standards which are then interpreted in individual cases by a delegate of the Secretary of the Department of Health and Aged Care. With relation to food the Australian New Zealand Foods Standards council has the power of veto over general standards but does not specific cases which is controlled by ANZFA. Submission No.77, p.111 (IOGTR) to the Senate Committee :
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

- non binding codes (policy guidelines, codes of practice, technical guidelines and procedural guidelines) and
- external review.

These sources provide a general policy platform that can be utilised, not to *direct* the way standards are set by the Regulator, but definitely to *influence* the process in which standard setting occurs. The degree of influence they have on unfettered discretion will ultimately be dependent on both how binding they are and how they are incorporated into decisions on where the standard balance should lie. The following two chapters deal with how discretion is fettered within a technological risk regime like the GTA. The first deals with the direct statutory fetters within the GTA. These are the jurisdictional limitations upon the Regulator set out under the object and framework clauses and the procedural obligations within various sections of the Act. The second examines the non-statutory fetters, such as codes, guidelines and principles.

10.1 OVER-REACHING OBJECTS

In principle the most specific statutory fetter is the jurisdictional limitation of the legislation which empowers the decision-maker. The objects and framework clauses of the Act set the scope and aims of the legislation and are used to prescribe the general limitations on administrative activities under the Act. The objects clause (section 3) of the GTA has been discussed elsewhere [see 4, 8.1] and simply states that the Regulator must protect against risks posed to the health and safety of people and the environment. The clause is expanded by section 4 of the Act, which describes the regulatory framework to achieve that object. I will discuss each of the obligations set out in these two provisions below.

10.1.1 HUMAN HEALTH AND THE ENVIRONMENT

Whilst the objects clause obliges the Regulator to manage risks in a way that protects human health and the environment it at no stage describes what degree of protection is necessary. Hence, there is cause to question whether the objects

clause has any direct influence on the standards the Regulator will set. Given the Regulator must decide on potential harm rather than actual harm (the risk dilemma) this point seems to hold even greater weight.

Thus, the objects clause does little to direct or circumscribe administrative discretion. Rather, it is more of a benchmark against which standards may be scrutinised, by superior bodies, the courts or the public. However, because of this it *does* introduce a degree of objectivity into what may have been a subjective assessment. This is because it obliges the Regulator to take into account what other bodies may consider to be a risk to health or a risk to the environment. Whilst of course this is only retrospective scrutiny, the mere potential for review may in fact play some part in the decision making process.

In the absence of concrete proof of damage Courts are likely to be extremely reluctant to intervene in the decision making process unless it was 'manifestly unreasonable' not to expect damage.[3] So while this over-reaching principle is influential upon standard setting by the Regulator it compels no specific mandatory behaviour.

10.1.2 'EFFICIENT AND EFFECTIVE'

Sub-section 4(a) of the Act states that the protection of human health and safety must be ensured through an 'efficient and effective system'. This requirement has two connotations:

- it reflects Parliamentary intention to create a efficient and effective *regulatory architecture*; and
- it suggests that operation of that system (that is risk management/standard setting)must be efficient and effective.

This begs the question, efficient and effective to whom, and to what degree? 'Efficiency and effectiveness' to an extent connote an economic rationale behind

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[3] *Queensland v Commonwealth* (1989) 167 CLR 232 ; *Minister for Aboriginal Affairs v Peko-Wallsend Ltd* (1989) 169 CLR 379 [63 ALJR 561; 87 ALR 412], Mason J at 41; A-G (NSW) v Quin (1990) 170 CLR 1at 37 *Assosciated Provincial Picture Houses Ltd v Wednesbury Corporation* [1948] 1 KB 223.

the GTA. Whilst not actually declaring that the Regulator should take economic considerations into account, the Act does, by using this phrase, suggest that standards must be set in a way which are streamlined, cost and time effective. Senator Brown of the Australian Greens objected to the phrase because:

> the object [protecting against risks] disappears in the application, which becomes an 'efficient and effective system' for allowing gene technologies to be applied.[4]

What Does the Phrase Mean? Outside section 4(a) there is no explanation as to how efficient and effective regulation is to occur, nor does it attempt to define either of these terms. An examination of other Commonwealth statutes however, provides some indication to what legislative drafters may have intended in including it under the GTA.

The phrase 'efficient and effective' is used in several Commonwealth statutes where it is most often associated with use of resources or funding. It is most frequently referred to in the *Federal Financial Management and Accountability Act* 1997(Cth).[5] In that Act, it is variously used to denote the proper use of the public purse and public resources.[6]

Perhaps a better example is the use of the phrase in the *Environment Protection And Biodiversity Conservation Act* 1999 (Cth) where it is specifically stated that there must be 'efficient and effective' utilisation of the 'resources allocated' for the purposes of the Act.[7] In that case it is clear that the phrase connotes the proper use of monies controlled by the Regulatory agency in question. The GTA however makes no specific mention of 'resources allocated' so the opposite may be true and the phrase may connote a proper consideration of the licensee's resources.

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[4] Brown B, 'Gene Technology (Consequential Amendments) Bill 2000 … Second Reading', 7/11/2000, p 19307.

[5]Being an Act expressly dealing with proper use of federal monies by federal agents.

[6]ss. 44, 44a, *Financial Management And Accountability Act* 1997 (Cth); Reg 9 (B) *Financial Management And Accountability Regulations* 1997 (Cth).

[7] ss 37 (f), 271(3)(b), 274 (f), *Environment Protection And Biodiversity Conservation Act* 1999 (Cth).

That the obligation to be 'efficient and effective' might require the Regulator to take into account the impact of regulating on licensees, finds support in several Commonwealth Acts relating to the regulation of primary agriculture. [8] In those acts it obliges administrators not to set fees or levies which might unduly impact on primary industry. This would also accord with the judicial interpretation of the phrase under the *Federal Court Of Australia Act* 1976 (Cth), which was taken to oblige the provision of 'cheap' and 'time efficient' services.[9]

What is clear then is that even thought the GTA does not specifically mention that standards must be set with reference to economic considerations, there is an intention they are to be taken into account. Moreover, because the Act is unclear as to *who's* resources must be used 'effectively and efficiently' the Regulator seems to be required to consider both the Office of the Gene Technology Regulator's (OGTR) and the licensee's economic well being.

More Than a Benchmark? It was noted above that the over reaching principle to protect human health and the environment was generally no more than a benchmark against which retrospective scrutiny could occur. The same may be generally true of the requirement to ensure an efficient and effective regime. However it was also noted that the potential for scrutiny may become an active part of the decision to set a standard should there be a likelihood of detection and review.

Licensees have access to the Courts to challenge decisions both administratively and meritously.[10] The economic effect of a decision is likely to be both immediately apparent and a sufficient cause for mounting an action. Unlike the extremely complex information associated with risk of harm to human health and

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[8] s.3 *Horticultural Export Charge Collection Act* 1987 (Cth), s.3 *Primary Industries Levies And Charges Collection Act* 1991 (Cth).

[9] *James Wong & Anor v Silkfield* Pty Ltd [1998] 27 FCA (16 January 1998). In that case the phrase had been used in Part IVA Federal Court Act. The Court held that the phrase was used to describe a system in which groups of people could obtain redress in a 'cheap' and 'time efficient' manner (a class action). Note that this case was overturned *Wong v Silkfield Pty Ltd* [1999] HCA 48, on different grounds (the definition of 'substantial common issue of law or fact') the interpretation of efficient and effective was not overturned by the High Court.

[10] s.19, GTA.

the environment, economic considerations are often translatable, obvious and easy to understand. Whilst a Government Minister may be unable to understand the concept of gene stacking, they are likely to conceptualise the pecuniary impacts of a licence condition. So ironically, superior bodies (non scientific) and the public may have a greater level of actual scrutiny on the resource allocation measures within standards than the quality of the standards themselves.

10.1.3 PRECAUTIONARY PRINCIPLE.

Section 4(aa) of the Act provides:

> where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

This provision, which enshrines what is known as the 'precautionary principle' was not included in the original Bill. Rather the legislation had been designed to reflect, according to the Interim Office of the Gene Technology Regulator (Interim OGTR), a 'generally cautious approach'.[11] Such an 'approach' was rejected by many stakeholders, the Opposition and minority parties and led to a trenchant debate in the Senate about the inclusion of an explicit principle. The debate, and various positions of these parties is summarised in Appendix 6.

The precautionary principle derives from the German legal principle *Vorsorgeprinzip* that basically requires foresight, forward planning and avoidance of potentially dangerous activities. It has more recently found favour in several domestic and international laws and agreements, particularly those relating to the environment.[12]

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[11]Submission No.77, p.74 (IOGTR); the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02)

[12] For instance: *Environment Protection and Biodiversity Conservation Act* 1999 (Cth); Inter-governmental Agreement on the Environment (IGAE) 1992, *Rio Declaration* (United Nations Conference on Environment and Development) 1992, *Biosafety Protocol* 2000.

A Pre-Emptive Protection. The precautionary principle is generally used to establish safe practices where there is scientific uncertainty concerning the nature or extent a risk. It imposes a general duty upon decision makers to take responsive action to minimise the potential for harm, rather than retrospective action subsequent to proof of harm itself.[13] However, this does not mean that any uncertainty should be avoided, because the risk dilemma is *inherently* about uncertainty. Rather the principle is an analytical tool for considering the data provided to a risk manager. It obliges the risk manager to consider both the information that risk assessment provided and the information that risk assessment may have missed, or been unable to provide. So in setting a standard the Regulator must consider what information may have been lacking in the risk assessment and factor this knowledge into the decision making process.

10.1.4 THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE TO STANDARD SETTING

To what extent will the precautionary principle set out in the Act influence standards under the GTA? Apparently it can only influence decisions where there is potential for environmental harm. This will obviously include releases into the environment but may also apply to the certification of facilities, level of containment and transport of GMOs [see 4.5]

The Act is silent on what degree of information establishes 'full scientific certainty' and this will seemingly be left to the discretion of the Regulator. Certainly, no risk assessment could ever guarantee complete scientific certainty, so the question is in fact what constitutes scientific *uncertainty.* This will of course be dependent on the discretion of the Regulator in light of any areas that are vague or uncertain in the risk identification and risk evaluation process. Basically the more rigorous, organised and defined the process of risk assessment the better the potential for discovering uncertainties. Inevitably however, the question will be one of the reasonableness of the Regulator's decision to set a

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[13] Coleman R, *The US, Europe And Precaution: A Comparative Case Study Analysis Of Risk In A Complex World,* Health and Consumer Protection Directorate, European Commission, Brussels, 2002.

standard based on certainty or the lack of it, because no formulation is provided within the GTA itself.

What constitutes 'cost effective measures' is also unqualified by the GTA. Determining what is cost effective would seem particularly hard because the nature of the precautionary principle is to identify a lack of certainty about risk. It would seem important to understand the scope of risk before any 'measure' for it's attenuation could be identified. By requiring the measure to be 'cost effective' the Regulator must effectively 'second guess' the risk assessment information to establish what the risk might be and hence what might be done about it.

A further concern about the meaning of 'cost effective' is against whom the evaluation will be cast. That is, would the evaluation be against the subject of the licence or will it be measured against any organisation? Would it be right to suggest that a multinational gene technology company should be assessed at the same level as a small or medium size start-up?

The lack of reference to human health in the GTA definition of the precautionary principle in theory permits the Regulator to disregard a lack of knowledge about the risks to humans posed by a proposed dealing. The political repercussions (to which the agency is not immune [see 9.4.3]) of treating risk data relating to the environment differently than that of human health are perhaps enough to ensure that the Regulator adopts a consistently cautious approach to all applications. Certainly there is nothing in the Act which specifically states that a precautionary approach may not be taken with respect to human health.

10.2 OBLIGATIONS SET OUT WITHIN THE ACT

The second mechanism by which the standard setting process may be influenced is through obligations set out within individual sections of the Act [see 4.6]. These provisions dictate the processes under which standard setting is to occur and the considerations which are to be taken into account.

Mandatory vs Directory Obligations. Before examining the actual obligations set out under the GTA, it is important to point out the form in which those obligations may be set out, and the result of non compliance with such obligations by the Regulator.

There are two primary forms of administrative obligation, mandatory or directory. The first is connoted by obligatory language such as 'must' or 'required' whereas the latter is primarily discretionary, described in terms such as 'may' or 'thinks appropriate'.[14] Mandatory provisions are obligatory and the Regulator is under a duty to observe them where applicable.[15]

To neglect a mandatory provision renders any decision invalid null and void.[16] Conversely a directory provision while being unlawful to disregard[17], is discretionary in operation[18] and failure to fulfil such a provision does not render the overall decision ineffective.[19] The rule is limited and may be applied flexibly in some circumstances, particularly where mandatory words would cause an unjustifiable inconvenience.[20] In such instances mandatory words may be read as directory by the Court.

10.2.1 GENERAL PROCEDURAL LANGUAGE WITHIN THE GTA.

Within the GTA, statutory influences upon the form and nature of standards tend to be phrased in directory rather than mandatory terms. Provisions relating to licence conditions generally use the term 'may', connoting discretion on the part of the Regulator to pick and choose standards that suit the form and extent of

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[14] see generally, *Grunwick Processing Laboratories Ltd v Advosry, Concilation and Arbitration Service*[1978] AC 655, *Tilbury & Lewis Pty Ltd v Marzorini* [1940] VLR 245, *Clayton v Heffron* (1960) 105 CLR 214.

[15] sub.33(1) *Acts Interpretation Act* 1901 (Cth).

[16] *Clayton v Heffron* (1960) 105 CLR 214 at 247.

[17] *ibid.*

[18] s.33. 2A *Acts Interpretation Act* 1901(Cth).

[19] *Clayton v Heffron* (1960) 105 CLR 214.

[20] *Tilbury & Lewis Pty Ltd v Marzorini* [1940] VLR 245.

dealing.[21] These powers broaden the ambit of regulatory discretion rather than narrow or focus it. The procedure for the construction and expression of standards are similarly directory. So for instance Notifiable Low Risk Dealings (NLRDs) [see 4.5.2] may be expressed to apply to classes of dealings, specific sub classes of dealings or several classes of dealings.[22] The review of standards are also left to the discretion of the Regulator, and there is no specific timeframe for review.[23]

Mandatory provisions with relation to the setting of standards are limited. Most requirements are procedural, obliging the Regulator to: maintain certain components of the scheme such as the register;[24] consider an application;[25] and prepare a risk assessment and risk management plan.[26]

The Act does not establish fixed ceilings on activities, except to delineate between brackets (brackets are discussed above [see 6.2]). For instance, a NLRD must not be released into the environment, thereby separating it from a licensed dealing. However, not all contained dealings are to be NLRDs and some will be licensed [see 4.6]. The Act does not clarify the types of contained dealings that must be licensed nor the threshold at which such dealings become NLRDs. Similarly, dealings on the Register [see 4.5.3] must have been previously licensed,[27] but the Act is silent on the length of time that dealing has been licensed or the number of licenses issued for that dealing.

10.2.2 CONSIDERATIONS

The Act contains mandatory provisions relating to 'considerations' that the Regulator must take into account in standard setting. Decisions that are made

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[21] The regulator may place conditions dependent upon the scope of dealing; purpose; variations; documentation; required level of containment; waste disporsal; measures to mitigate risks; data collection; auditing; actions in case of breach; geographic area; contigency planning; limiting dissemination of GMO into the environment [s.62, GTA].

[22] ss. 74(4), 75 GTA.

[23] s.144, GTA.

[24] sub.76(2), GTA.

[25] s.43, GTA.

[26] s.47, GTA.

[27] s.78, GTA.

without reference to mandatory considerations and which cannot be linked to considerations set out under the Act will be deemed *ultra vires* and void.[28] The decision is rendered similarly invalid where mandatory considerations have not been taken into account.[29] This effectively sets the absolute limits on the decision-making activity. Yet those limitations can be illusory where the considerations allow a broad ambit of discretion, or are primarily subjective.[30] Furthermore the degree to which considerations circumscribe unfettered discretion is entirely dependent on the interpretation of the words 'consider' or 'take into account'. Where the legislation is not express as to the weight given to advice and considerations, the issue of weight will be one of personal judgment by the decision maker, and the Courts will rarely intervene.[31]

Mandatory Considerations May Be Subjective. Whilst the requirement to 'consider' something may be phrased in mandatory language, it does not actually compel the Regulator to act in any specific way. Mandatory considerations seem to 'impose' primarily subjective and paradoxically discretionary requirements. Moreover mandatory considerations are often obliged for what seem to be subjective judgments anyway. For instance, the Regulator can only declare a dealing to be an NLRD, if she or he consider it to pose minimal risk and require minimal conditions to ensure its safety.[32] The Act however does not specify the level or risk which is minimal nor the level of risk which is hazardous. Similarly when setting the standards for the use of a GMO the Regulator must 'take into account' the risks of that dealing 'having regard to' a variety of potential risks[33] and 'take into account' means of managing those risks.[34] Therefore, mandatory language often does not actually oblige any action whatsoever, [35] and may have little influence on the outcome of a decision.

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[28] subs. 5(1)(b), 6(1)(b) *Judicial Review Act* 1977 (Cth).

[29] *ibid.*

[30] *Project Blue Sky v Australian Broadcasting Authority* (1998) 194 CLR 355 at 91-93.

[31] *Chapman, and Ors v Tickner, And Ors*, (1995) 55 FCR 316 par 159.

[32] s.74(3), GTA.

[33] Including the, Properties of GMO, Effect of modification on the organism, Provision for limiting the dissemination of that organism, Potential for spread, Extent or scale of dealing, Impacts on human health or the environment, Other matters prescribed by regulations. [subs.49(2) (a)-(f), GTA; sub.51(1)(a), GTA.]

[34] s.51, GTA.

[35] *Project Blue Sky*, *op cit*, 30.

Mandatory Considerations Do Not Oblige Action. Mandatory *considerations* do not of themselves direct standards, they are guides to the creation of standards. They do not denote the degree of harm or acceptable level of interference in activities. Rather, they are a number of factors which the Regulator must be aware of in the setting of the standard but no more. So despite the existence of mandatory language these are administrative requirements, which in practice are influential but not binding upon the standard setting process. Subsequently, it merely needs to be shown that the proper factors were taken into account during the standard setting process.[36] There is no need to show that the standard set equates with the will or spirit of Parliamentary intention but merely that the right boxes have been ticked.

10.2.3 CONSULTATIONS

In deciding to licence a dealing that involves an intentional release into the environment and in applying any standards upon that dealing, the Regulator is required to consult with a variety of bodies. These include State Governments, the Gene Technology Technical Advisory Committee (the Technical Committee), Commonwealth agencies or authorities, the Environment Minister and local councils.[37] In all but a few instances it is at the Regulator's discretion to consult such bodies.[38] The Regulator has directory powers to take into account any other advice relevant to the decision.[39] With respect to licenses for contained dealings the need to consult the above bodies is directory only.[40] There is no requirement to consult any of the above bodies with respect to NLRDs, exempt dealings, listings on the Register, certification or accreditation.

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[36] *Chapman v Luminis Pty Ltd* (No 5) [2001] FCA 1106 (21 August 2001).

[37] ss 50(3), 51(1)(c)-(f), 51(2)(d) , 52(3), GTA.

[38] The Regulator must consult relevant bodies in the case of ; risk assessment and management [ss 50(3), 56(2) GTA.]; revocation of a licence [s.72(4) GTA.]; Revocation or suspension of certification [s. 89(4) GTA.]; suspension or cancellation of accreditation [s. 97(4) GTA.].

[39] s.51(3), GTA.

[40] sub.47(4), GTA.

No Direct Influence From Committees. The nature of consultations is strongly tied into the issue of independence outlined above [see 9.2]. Because the Regulator cannot be directed by anyone in relation to individual decisions, the ability of external agents to influence individual standards is automatically limited. This diminishes the role of the Technical Committee, the Ethics Committee and the Community Committee because they can only ever act in an advisory capacity. The committees have no power to initiate independent investigation or provision of advice to either of their superior bodies. Rather, their operations are contingent upon a request from the Regulator or Ministerial Council.[41] Where the committees provide advice, there is no obligation to give that advice any more weight than that of any other body consulted.

No Direct Influence From Other Tiers Of Government. External bodies, who may have been assumed to be given greater weight in certain circumstances, are not provided any primacy by the Act. States or local councils in whose jurisdiction an activity will take place are given no automatic right of veto over those activities. Nor does the Act specifically accord such bodies with any more say in the standards applied than other bodies or indeed Governmental organisations in other jurisdictions.

No Direct Influence From Environment Minister. During debate over the Gene Technology Bill several groups voiced their concern over the weight given to the advice of the Environment Minister.[42] They suggested that the Environment Minister should have veto rights over released dealings with GMOs while some others extended this further arguing that the release of GMOs was a matter of national environmental significance. Under the *Environment Protection & Biodiversity Conservation Act*, matters of national environmental significance require approval from the Minister for the Environment and Heritage.[43]

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[41] ss.101,107,112, GTA.

[42] Submissions No.86, p.2 (WWF & HSI); No.85, p.8 (ACF GeneEthics Network). the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[43] Environment Protection And Biodiversity Conservation Act 1999 (Cth)

All suggestions for the decisions of consultative bodies to be given more weight, or for those bodies to be accorded veto rights in certain circumstances, were rejected.[44] External binding considerations were generally seen as causing undue and unnecessary overlap.[45] For instance the Senate committee rejected the suggestion that the Environment Minister be involved in open release dealings. Instead it recommended that provisions for the protection of the environment should 'parallel' the current *Environmental Protection and Biodiversity Conservation Act*, rather than outsourcing decisions to it.[46] The Government echoed this stance arguing that by allowing others veto rights or binding considerations in any circumstances would lead to 'bureaucratic nightmare of boards and committees, and anonymous backroom regulation'.[47]

The reticence to allow the Minister for the Environment to participate in the decision making process seems to be based on a perceived need to maintain a unified and transparent risk management. However this stance appears contrary to the GTA status as 'gap-filler' legislation. If authorities such as the TGA or ANZFA must consider GMOs which fall within their respective jurisdictions [see 4-4.1], how does the Environment Minister's consideration of the impact of organisms released into the environment have any more or less an overlapping aspect?

Maintaining Objectivity. A further argument for limiting the veto power of external bodies was that it would impact on the neutrality and objectivity of the risk management process.[48] This does not clarify why some external Federal agencies maintain their right to regulate GMOs whilst others like the Environment minister do not. The argument does however, provide rationale against extending the scope of the internal committees beyond mere advisory bodies. It emphasises the importance of an impartial arbitrator to consider information from various

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[44]Tambling G '*Gene Technology Bill* 2000 … Second Reading' *Senate Hansard,* 8/11/2000, p 19369.

[45] *ibid.*

[46] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, para 4.85.

[47] Tambling G, '*Gene Technology Bill* 2000 … Second Reading' *Senate Hansard,* 8/11/2000, p 19369.

[48] Environment Australia, *The Community Expects Neutrality.* Report to the House of Representatives, Environment Australia, Commonwealth of Australia, Canberra,2000 p. 21.

sources. The risk assessment process may present rather conflicting and contrary data to the risk manager. As one Senator noted, the field is caught up in 'a minefield of claims and counterclaims about the benefits and dangers of genetically modifying organisms.'[49]

Each specialist body within the GTA regime focuses on a unique area of gene technology risk, be it the human health, environmental, ethical, industrial and so on. The relative importance any one body will accord to each area is likely to be directly influenced by that body's contemporaenity to it. The specialisation of these bodies invariably narrows the scope of deliberation on issues outside their field. Disagreement may also arise within groups themselves (given the considerable number of experts in each).

Providing veto rights to any of the Committees, or to outside bodies would likely result in disagreement about the importance of various factors which need to be taken into account during risk management. Whilst all views should be considered, giving each equal or even differing degrees of weight would be logistically difficult and lead to prolonged deliberations. In a system designed to be 'streamlined' such an outcome is likely to be unwelcome, because it would increase the costs of regulation and the time which licensees would be required to wait for approval.

10.3 BINDING CODES (POLICY PRINCIPLES)

Policy principles are binding codes that are intended to either directly limit or elucidate the ambit of discretion by the Regulator and therefore influence standard setting. These principles will generally relate to ethical issues or State designated genetic modification free zones (GM free zones).[50] There is no provision within the Act to extend the principles to either human health or the environment. However the scope of policy principles may be broadened via the Regulations, so

[49] Gibbs B, 'Gene Technology (Consequential Amendments) Bill 2000 …: Second Reading' *Senate Hansard*, 7/11/2000, p 19304.

[50] subs.21(1)(a)-(aa) GTA.

long as the extensions to policy principles do not derogate from the health and safety of people and the environment.[51] Furthermore while they apply to the ethics of dealings with GMOs they do not apply to ethical issues regarding Gene Technology.

Policy principles are formulated by the Ministerial Council [see 4.2] in consultation with all committees, any Commonwealth and State agencies, industry, environmental, or other groups deemed appropriate.[52] The Regulator may be requested to draft or assist in drafting policy principles.[53]

Where a policy principle has been enacted, the Regulator cannot grant a licence which would conflict with the principle[54]. Indeed, if the Regulator is satisfied that an application would breach a policy principle she or he needn't even consider the application.[55] Policy principles are however, limited to licensing decisions and not to other standards which the Regulator may set.

Limitation on Policy Principles. Policy principles do not apply to any lower level bracket standards (NLRDs, Exempt, or Registered Dealings [see 4.5]). A literal reading of the Act would seem to indicate that in the exercise non-licensing functions, the Regulator is not actually bound to apply policy principles set down by the Ministerial Council. However, in the majority of instances this oversight will have little affect on the day-to-day operations of scheme, as the majority of non-licensing functions established under the Act are in fact incidental or intrinsically linked to the licensing process.

If an activity is banned by a policy principle and hence does not entering the scheme it would seem unnecessary to apply that policy principle to lower level brackets. However, this also means that policy principles only apply to future licenses. Hence, changes to, or the creation of, new policy principles would seem not to affect existing activities under the legislation. Policy principles then, seem

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[51] subs.21(1)(b), 21(3), GTA.

[52] s.22, GTA.

[53] sub.27(b), GTA.

[54] sub.57(1), GTA.

[55] sub.43(e), GTA.

not to apply retrospectively to dealings which have been moved into lower level brackets nor existing licenses as the Regulator must only consider policy principles in the issuance of a new license.

Perhaps of more concern to some opponents of GMOs, including States such as Tasmania is the fact that exempt dealings will not be subject to policy principles. Therefore, the recognition of GM free zones will not apply to dealings declared by the Regulator to be exempt from regulation. Given there are no statutory requirements on how and why dealings may be declared exempt it is possible that such dealings need never to have entered the licensing bracket and thereby bypass the scheme and policy principles altogether.

The advisory role of the Regulator to external agencies such as the Therapeutic Goods or Agricultural and Veterinary Chemicals [see 4] will also remove the Regulator from the scope of policy principles. In these situations the Regulator will not be actually issuing a licence – even though the good or activity will involve the use of a GMO – and therefore will not be bound to consider, or even recommend compliance with, a policy principle.

The Weight of Policy Principles. Policy principles are intended to ensure that an elected body can influence the scope of regulatory discretion and apply broad standards, which will be applied to all dealings. As such, they should be the strongest prescription on the Regulator's discretion. Yet, by extending policy principles only so far as ethical issues and GE free zones, the core risks that the Act deals with – namely human health and the environment – will remain outside the direct control of the Ministerial Council. Certainly this ensures the independence of the Regulator, however, a level of independence would have been maintained nonetheless, given the principles could only be applied in a broad, rather than case by case, way. Whilst the GTA does allow for the Regulations to expand the scope of the principles this has not as of yet been utilised by the Government. Hence, the influence of the principles remains minimal and will not specify how scientific data should be interpreted, what level of safety should be ensured or how risk should be quantified and responded to.

10.4 NON-BINDING CODES (GUIDELINES AND CODES OF PRACTICE)

Policy guidelines are non-binding influences on standards. The issuance of such guidelines is a sole matter for the Ministerial Council and there must be mandatory consultation with each committee, any Commonwealth and State agencies, industry, environmental, or other groups deemed appropriate.[56] The guidelines may apply to 'matters relevant to the functions of the Regulator'.[57]

Policy guidelines are not mandatory, although the Regulator is bound to 'regard' them during the licensing process.[58] As argued previously, [see 10.2.1] the need to have 'regard' to something is more a directory influence than a mandatory restriction. Whilst the Act states that policy guidelines are to 'relat[e] to matters relevant to the functions of the Regulator',[59] they are not expressly mentioned outside of the licensing provisions.

Like policy principles, policy guidelines are binding only on licence dealings and not lower level brackets. Furthermore policy principles need only be 'considered' by the Regulator where a dealing may pose risk to human health or the environment.[60] The implication being, that the Regulator needn't consider policy guidelines associated with the ethical, general or community concerns relating to GMOs.

Codes Of Practice. The Act makes provision for the Ministerial Council to issue 'codes of practice'.[61] There is no description within the legislation as to what constitutes a code of practice, how it is to affect decision-making or indeed who it applies to. The explanatory memorandum for the Gene Technology Bill describes codes of practice as follows:

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[56] sub.24(2), GTA.

[57] s.23, GTA.

[58] s. 56, GTA.

[59] s.23, GTA.

[60] sub.56(d), GTA.

[61] In consultation with each committee, any Commonwealth and State agencies, industry, environmental, or other groups deemed appropriate [s.24 GTA.].

> In the same way that the Regulations will detail matters mentioned in the Acts, codes of practice … detail matters raised in the Regulations. That is, they provide an additional level of detail about specific matters of concern. For example, codes of practice may be developed by the [Regulator], in consultation with stakeholders, to explain the detailed requirements for certification of facilities.[62]

Codes of practice may be required as a condition of a licence or obliged by the Regulations.[63] Unlike policy principles and guidelines these are standards in themselves rather than measures which apply to the standard setting process. Furthermore, the Ministerial Council, rather than the Regulator sets them. Like policy guidelines, the actual influence of the Ministerial Council over these standards is somewhat proscribed by the GTA framework. This is apparent for several reasons.

First, a code of practice can only be required as a licence condition. This means the application of a code of practice is ultimately at the discretion of the Regulator because the imposition of licence conditions is a directory obligation under the Act [see 10.2.2]. Second, while the Regulations may require compliance with a code of practice, it is the Regulator who has the most effective control over the form and content of the Regulations. [see 10.5.1]. Finally, section 27 of the Act makes the 'development' of a code of practice a function of the Regulator, rather than the Ministerial Council.[64] Evidently, the Act intends that the roles of Ministerial Council and Regulator are separate. It uses the phrases 'issue' (Ministerial Council) and 'development' (the Regulator) respectively to denote their individual roles but goes no further to set out what these phrases mean. In essence this divide would indicate that it is actually the Regulator who is

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[62] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra, p 12

[63] ss.62, 193, GTA. There is a slight uncertainty as to the exact extent of section 193 (GTA) , which allows the regulations to oblige a 'person' to comply with codes of practice. There is no mention of an 'organisation' within this section. 'Person' is not defined within the Act so it is unclear what is meant in this context.

[64] sub.27(b), GTA.

responsible for the formulation, creation and drafting of codes of practice and that the Ministerial Council undertakes the formalities of *enactment*.

10.5 SCRUTINY OF THE STANDARD SETTING PROCESS.

As previously explained, the Regulator is immune from external direction with respect to licensed dealings.[65] Several suggestions were put forward at discussions over the Gene Technology Bill to allow for the Ministerial Council to veto or strengthen licence standards.[66] Like suggestions about increasing the power of advisory bodies the concept was rejected because of the impact on the Regulator's independence. [67]

So, whilst the Ministerial Council – and thereby Parliament – is to have an influence on broad standards (set in advance of risk assessment and risk management), the Regulator will remain largely independent with respect to narrow standards (those set during risk assessment and management). This was designed to ensure that 'decisions of the Regulator are scientifically based, clear transparent and independent'.[68] Yet it will also shield the Regulator from a large degree of review from superior bodies, regardless of the nature or outcome of the decision. Less stringent brackets (NLRDs, Registered and Exempt Dealings) which are governed by broad, generalist standards (and hence fall outside section 30) are however subject to some Parliamentary scrutiny prior to their implementation.

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[65] s.30, GTA.

[66] Submissions No.17, p.4 (National Genetic Awareness Alliance); No.54, p.6 (OFA); to the Senate Committee :

<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[67] Interim Office of the Gene Technology Regulator, *Proposed National Regulatory System for Genetically Modified Organisms – How should it work?* Draft Discussion Paper for Consultation, Commonwealth of Australia (AGPS), Canberra, 1999, p 20.

[68] *ibid.*

10.5.1 PARLIAMENTARY AND MINISTERIAL SCRUTINY

Scrutiny and review of standards are extremely important to maintaining transparency, visibility and accountability. They ensure that objectivity is built in to decision-making.

It is important here to define what is meant by scrutiny, because it could be taken to mean review by courts or tribunals after the standard is set and applied. The potential for such review will definitely influence the decision making process. However, the current discussion concentrates on statutory prescriptions on the *enactment* of standards not the affecting of them once in place. Subsequently when I refer to 'scrutiny' I refer to legislative measures which grant exterior bodies (such as the Ministerial Council or Parliament) the ability to participate in, or oversee, the standards setting process. The most basic form of scrutiny is the review of standards by a superior body before they come into effect. At the other end of the scale is the active setting of standards by a superior body.

NLRDs and exempt dealings are specified within the Regulations. Any variations to the Legislation or Regulations are, by virtue of the *Commonwealth Acts Interpretation Act*, required to be subject to review by the Commonwealth Parliament.[69] Indeed, under the GTA, it is the Ministerial Council, rather than the Regulator, that is responsible for their implementation[70] and the Governor General who is responsible for their declaration.[71]

How Effective Is Ministerial Oversight? Whilst in principle, Parliament and the Ministerial Council oversee the setting of broad, non specific standards, their level of actual participation in the formulation of standards is less influential than it might first appear. It is the Regulator who initiates review of whether dealings should be listed as NLRDs or exempt dealings.[72] There is no provision for the Ministerial Council to independently initiate such a review. If the Regulator considers that a NLRD or exempt dealing should be added or varied, she or he

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[69] see pt XII, *Acts Interpretation Act* 1901 (Cth).

[70] s.143, GTA.

[71] s.74, GTA.

[72] ss.40,141, GTA.

may publish a notice inviting written submissions.[73] This is a directory obligation only.[74] Hence, unlike the extensive community consultation process for the enactment of regulations proper, variations to those Regulations could, in some circumstances, occur without such community discussion. Furthermore, it is the Regulator and not the Ministerial Council who must consider whether the dealing meets the criterion of a NLRD.[75] Only once the Regulator undertakes these various considerations and procedures are recommended amendments to the Regulations presented to the Ministerial Council.[76]

What is unclear in the legislation is whether the Regulator or Ministerial Council is to draft amendments. Given the scientific nature of the subject matter it is likely to be the former. Furthermore there is no requirement for the amendments to be verified by appropriate committees (such as the Technical Committee), or outside bodies. The legislation sets out no protocol for the acceptance, amendment or refusal to accept a recommendation by the Ministerial Council. Although the Ministerial Council may consult the committees with regard to the need for and content of policy principles, policy guidelines and codes of practice, this consultative power is not extended to variations of the Regulations that would create or amend NLRDs or exempt dealings.[77] Whether this is the case in practice is yet to be seen.

Once agreed to by the Ministerial Council, amendments must be published or notified in a relevant Government Gazette, and tabled before both houses of Parliament within fifteen days of being made. They are subject to disallowance for a period of another fifteen days after being laid before the house.[78] The Act also makes other subordinate rules subject to disallowance. These include Policy Principles[79], Codes of Practice[80] additions[81] and variations[82] to the GMO register.

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[73] From the public, States, GTTAC and relevant Commonwealth agencies [s.142, GTA.]

[74] s.144, GTA.

[75] Specifically that it does not involve an intentional release into the environment, is biologically contained, involves minimal risk, whether there should be any conditions, [subs.74(2),74(3), GTA.]

[76] sub.143(2).

[77] ss.101,107,112, GTA.

[78] subs.48(1)-(4) *Acts Interpretation Act* (Cth) 1901.

[79] sub.21(4), GTA.

[80] sub.24(3), GTA.

Policy Principles, procedural and technical guidelines are not subject to disallowance.

Informed Review. The involvement of the Ministerial Council and Parliament in the implementation or disallowance of regulations certainly restricts the ambit of the Regulator's discretion with respect to standards. Yet, for all intents and purposes, it is the Regulator who plays the predominant role in the initiation and design of those very Regulations.

As noted above, the Act makes no explicit provision for the Ministerial Council to consult any of the committees for advice regarding the alteration of the Regulations. It is less likely that Parliament will have access to the advice of the expert committees. There is no requirement for any of the committees to agree to changes to the Regulations, or for that matter to be consulted. However, should a committee disagree with the changes, would Parliament be privy to this advice? In tabling the amendments before the houses, will such amendments be explained in detail or indeed in 'plain english', so as to facilitate informed debate? Without expert advice or a clear understanding of the complex lexicon and science of gene technology, review by Parliament is likely to be no more than a matter of protocol.

The Need For Expedience. The explanatory guide to the Gene Technology Bill states,

> Recognising that the technology is changing very rapidly, it is important to regularly review the GMOs and dealings prescribed as notifiable low risk dealings and exempt dealings. This will keep up to date with the latest scientific developments and information regarding any risks.

Evidently the nature of the technology makes such a streamlined and flexible process necessary. Yet this would suggest that measured and considered debate will be kept at a minimum. The intention to create an expeditious process,

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[81] sub.78(4), GTA.

[82] sub.80(3), GTA.

coupled with the dominant role played by the Regulator, would seem to indicate that external scrutiny is more a formality than a direct influence on the setting of standards.

10.5.2 THE DEGREE OF FETTER

In all, the direction of standards from within the legislation is minimal. The main source of fetter upon standard setting is the obligation to 'consider' various matters. In law, such considerations must be given genuine and realistic consideration[83] and form a fundamental element in the decision making process.[84] To discharge the obligation the Regulator needs to show satisfactory evidence or documentation that the matter was read and played some part in the decision making process.[85] In practice this could be taken to be merely an administrative requirement.

Like the over-arching objects clause, mandatory considerations really provide for a third party to objectively review a decision at some later date. Whilst they have little direct effect on the decision making process, the chance of review will always be factored into the decision to set a standard. However, the impact of potential review is questionable. The Act does not indicate which factors are more relevant than others, or what weight should be afforded them. Nor does it set absolute ceilings on activities. Such requirements can and do facilitate an environment where a decision is an informed one. Yet they cannot be said to prescribe the quality of that decision. Courts are extremely reluctant to involve themselves in deciding whether relevant weight has been given to one consideration over another, particularly where the legislation is less than prescriptive on the issue.[86] Moreover, the Act specifically limits merits review to licence holders, so the potential for review diminishes all the more.

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[83] *Khan v Minister v Minister for Immigration and Ethnic Affairs* (1987) 14 ALD 291.

[84] *Tickner v Chapman* (1995) 57 FCR 451 [89 LGERA 1; 133 ALR 226.

[85] *Sean Investments Pty Ltd v MacKella*r (1981) 38 ALR 262, per Dean J at 370; *Tickner v Chapman* (1995) FCR 451.

[86] *Minister for Aboriginal Affairs v Peko-Wallsend Ltd* (1986) 162 CLR 64.

If the variety of considerations, obligations and objects are generally directory, why are they phrased in mandatory language? Such a question was indeed put by Thompson MP to the House during the debates over the Gene Technology Bill. Thompson MP, an ardent industry supporter, criticised the voluminous number of considerations within the Act as effectively slowing the approval process. In the end however, he relinquished to the requirement to seek advice and consider various factors, because these 'duties' were unlikely to affect the outcome of a decision in any overwhelming way. [87] The various considerations and objects, he concluded:

> seems to me to be put in there for the purpose of satisfying a rather strident lobby that something is being done, but as to what the outcome is, that is a bit of a mystery.[88]

10.6 CONCLUSION

The degree of independence of the Regulator to set standards is broad. Not only is the Regulator immune from direction on individual standards, she or he will play the *primary* role in the formulation of general standards, including those which are intended to influence the standard setting process. Similarly, external involvement in the standard setting process is minimal or at the discretion of the Regulator.

Regulatory independence was argued to be central to ensuring that the risks posed by gene technology were governed in an objective and impartial manner and not captured by either side of the debate. Yet the conflation of independence and impartiality is, I believe, a misnomer. Independence does not lead to impartiality; in fact, it can do the exact opposite.

Whilst the terms independence and impartiality were often conflated in Parliament and in public, it seems that in reality Government saw them as mutually exclusive objectives. Extra measures to further impartiality such as: establishing a statutory

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[87] Thomson A, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 28/8/2000, p 19470.

[88] *ibid.*

authority; ensuring greater external scrutiny of risk management decisions; involvement of other agencies in risk management; and making the Committees active participants in standard setting; were usually dismissed as somehow impacting on the independence of the Regulator. Yet this begs the question, why have independence in the first place? If independence was truly intended to ensure impartiality, then there is little point arguing that measures specifically designed to *guarantee* impartiality impact upon the 'independence' of the Regulator. The argument is cyclical and nonsensical.

Perhaps a more suitable explanation for the heavy emphasis on independence was the concurrent push by Government and industry to streamline the standard setting process. From that perspective, the greater the number of bodies involved in reviewing information and making decisions, the longer it would take to realise commercial application of products. Hence, the concept of making the Regulator a statutory body of three decision makers was unattractive because it was perceived to introduce uncertainty and prolong the time between application and decision. Similarly, involvement by specialist bodies would, 'spoil the broth' so to speak, increasing the time and cost of the application process. In a competitive area like gene technology this was an extremely unattractive option both to industry and to a Government attempting to foster it. As Harl *et al* noted:

> Approval by domestic and foreign regulatory bodies [is] the final hurdle necessary before commercialisation and [is] aggressively sought. Huge financial investments in the development of these products and the need to begin showing returns … create a sense of urgency ... Biotech [gene technology] firms place a high premium on gaining rapid regulatory approval for these new products.[89]

The streamlining of standard setting is evident throughout the whole of the GTA. Broad standards are encouraged and as the regime develops will be applied to an increasing proportion of dealings. This will minimise regulatory intervention and to ensure that no overlap or duplicity occurs. Where individual standards must be

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[89] Harl N.E et al, 'The StarLink Situation', Biotech Info Net, Working Document, Rev. 10/25/00, 2000 : <http://www.biotech-info.net/0010star.PDF> (12/12/02).

applied they determined by an individual agent with minimal external influences that would otherwise slow down the process of commercialisation. Everything has been done to ensure expediency, even in the higher risk brackets. Should the regime become self-funding as anticipated originally, the streamlining of the standard setting process will likely become more acute.

Even should the regime not become self-funding, the very object of the Act requires that the standard setting process be economically efficient. The need to minimise the use of the resources and time, of both the Regulator and licensees, can be expected to create an impetus towards broader and broader standards. If this happens, borderline activities, that may previously have been considered to be deserving of greater regulatory intervention, could potentially slip into lower brackets. Yet the rational is self-perpetuating, so that as standards become broader, there is seemingly less need for Regulatory activity. This in turn provides a justifiable reason to limit Governmental funding or make the Regulator self-funding.

Protocol vs Process. Broad standards tend to suggest that a large number of activities fall under legislative scrutiny. Yet in practice they result in less actual scrutiny of individual activities. This is especially apparent where resources are minimised. Standards could in such circumstances be said not to *actually* control externalities, so much as to create the *appearance* of control. This emphasis on process rather than outcome is a definite theme throughout the GTA with respect to standard setting.

The lack of substantive standards within the Act and the lack of direct influence on the Regulator seem to indicate that process is more important than outcome. So long as administrative process is followed it is assumed that the resulting standards will reflect the proper balance between competing rights and interests. Such a premise assumes regulatory agencies are immune from bias and immune from political pressure. The long discourse of regulatory theorists on capture would seem to suggest otherwise.

PART III

DELIBERATIVE RISK GOVERNANCE

11

RE-INVOLVING THE PUBLIC : RISK COMMUNICATION

The discussion so far has examined how the public concern about the risks posed by novel technologies has led to the development and implementation of increasingly complex regulatory responses by governments worldwide. The quest to solve the risk dilemma and to normalise risks from nature by using technology, and from technology using law has resulted in the growth of specialised risk regulation. The modern form of risk governance ensures rule flexibility, the application of expert technological and scientific oversight, and the standardisation and adoption of international best practice, enabling it to be readjusted, reinvented or fine tuned based on emerging evidence, new techniques or technologies. In the modern blame society such regulation is necessary, because government is expected to intervene and take control of technology so that the people retain the right to be the final arbitrators of their own fate.

De-Involving the Public. The development of risk governance practice into the discipline that it is today has not totally succeeded in solving the risk dilemma. Rather, the expansion, streamlining and formalisation of risk governance has steadily – for the want of a better term – 'de-involved' the public from evaluating the changes caused by technology and asserting their concerns about it.[1]

[1] *pace* Kirby M, *Reforming the Law*, Oxford University Press, Melbourne, 1983, p 237.

The first way this has happened is through the slow attitudinal shift that has occurred with the evolution of the risk analysis paradigm. This shift marks a gradual narrowing of the risk concept so that technical assessment is orientated towards scientifically quantifiable, physical risks. This neglects the fact that the public generally tend to conceptualise risk within a broader context, considering any potentially harmful scenario – be it physical, ethical, social or economic – risky. Whilst the modern risk governance process recognises these concerns still exist, they are treated with a great deal of suspicion and sometimes described as 'illegitimate' of 'unfounded'. That process does not afford such risks the same level of rigorous scrutiny and systematic assessment that it does to scientific risks, and it seeks to restrain their influence on the decision making process.

The second way in which the public has been 'de-involved' from deciding their own fate is the gradual diminution of direct Parliamentary involvement in risk governance. This has a correlative impact on popular involvement in decision-making about risk, as Parliament is ultimately controlled by the people in a representative democracy.

Initially the diminution of control occurred through delegation of parliamentary powers to responsible officials. The sheer technicality and intricacy of novel technologies however has pushed the delegation even farther, so that 'risk experts' must participate in the process of assessment and management. Yet these processes have such a profound effect on the way the final decision is made, that – in all but name – risk experts become cooperative partners in the process of regulating.

Given that such risk experts are the actual subjects of legislation, the process is susceptible to returning decisions about risk, and hence social fate, to the very technocrats whom the public were so concerned about in the first place. Moreover, they are not government agents, and not ultimately responsible to the people for the decisions they make. Rather they are, understandably, responsible to the institutions for whom they are employed, and the shareholders who fund their products.

The third way that the public has been 'de-involved' is through the very need to ensure legislative flexibility discussed above. Because the legislative process is so cumbersome and relatively static in operation, Acts such as the *Gene Technology Act* 2000 (Cth) (GTA/the Act), must adopt bracket shifting, where standards are set through subordinate regulations, licenses, codes and principles. These allow differing standards to apply to differing activities and the ability to quickly implement new standards or update old standards where required. Yet to adopt and apply such standards effectively requires expertise, time and resources, which Parliament or indeed governmental ministers simply do not have.

As a result of the limitations of ministerial and parliamentary process, a Regulator rather than the Parliament or Parliamentary Ministers sets the majority of regulatory standards. Thus, Parliament merely establishes the skeleton of legislation and subordinate agents create and apply most of the practical law. Indeed, as can be seen in the GTA, even in those cases where bodies superior to the Gene Technology Regulator (the Regulator) do have the primary role in the creation or review of regulatory standards, the nature of the technology is such that, the Regulator will ultimately play a very large part in the formulation of such standards.

Of itself, the dominant role played by a regulatory office seems to blur the separation of powers doctrine by allowing the administration to effectively exercise executive and quasi-legislative powers. Concurrently it seems to deprive the populace of a degree of transparency and legislative responsibility which they would have under codified statute, where the standards are set internal to legislation and hence policy is clearly evident from the text itself.

Finally, the fact that Government has also become a proponent of technology, has meant that its role in objectively and impartially controlling the risks and benefits of technology is called into question. As a result, Parliament saw fit – when enacting the GTA – to create an independent authority (the Regulator), which acts largely outside of governmental influence. This was apparently intended to ensure that the decision making process was, and appeared to be, impartial and objective. Yet the problem is that independence does not automatically guarantee

either impartiality or objectivity. As such, it means that potentially subjective [see 9.3], or value laden [see 8.3.3] decisions about technological risk, are being made outside of the legislative process and largely unaffected by Parliamentary scrutiny.

The Control Paradox. The development of modern risk governance, particularly with the incorporation of the risk analysis paradigm has thus resulted in a control paradox. This means that the greater influence that regulation has upon technology the less influence the people, through the agency of the Crown, have in regulation. Thus, the control paradox means the people will be de-involved as modern technology becomes more complex, more dynamic and increasingly beyond the comprehension of lay people.

I do not wish for my critique of the modern risk governance process to be taken as an attempt to discredit it entirely, nor to advocate its replacement. My argument has consistently been that the risk dilemma demands a high degree of flexibility, and it requires a high level of expertise to solve. As Justice Kirby has very rightly argued,

> [u]nless interdisciplinary machinery can be developed, capable of consulting the experts … we must sadly face up to the inability of our democratic institutions to respond to the challenge of science and technology.[2]

There is not just a justification for risk governance to incorporate risk analysis and expert opinion; there is a necessity for it to do so. Thus, in a way, we must recognise the inevitability of the control paradox, because as a body limited in size and expertise, Parliament must delegate its power sufficiently far to ensure that it has effective and dynamic control over the technology. However accepting that a control paradox will arise is fundamentally different than accepting it fatalistically. Instead, the control paradox must be met with institutional mechanisms, which impel objectivity, oversight and scrutiny of those decisions to ensure they are objective and impartial and do not succumb to subjectivity and bias. Moreover, where we must necessarily look outside the law for mechanisms

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[2] *ibid*, p 238.

to solve the risk dilemma, and these mechanisms de-involve the public, we must strive, through law to ensure public re-involvement.

Regulating is About Balance. We must realise that risk regulation, where it utilises the risk analysis process, has the capacity to tip the balance against representative and responsible democracy. In order to ensure that the people retain the ultimate control over their fate we must build institutional mechanisms into legislation that tip the balance back towards a more representative and responsible process. To do any less would be to cede power back to the technocrats for whom the regulation was necessitated in the first place. Justice Kirby's response to the need to bring in technocrats to solve the risk dilemma was to argue:

> [w]e clearly need new and more effective institutions. We will need more dialogue between scientists and the community and scientists and lawmakers … Science and technology are advancing rapidly. If democracy is to be more than a myth and a shibboleth in the age of mature science and more than a triennial visit to a poling booth, we need a new institutional response. Otherwise, we must simply resign ourselves to being taken where the scientists' and technologists' imagination leads. That path may involve nothing less than the demise of the Rule of Law as we know it.[3]

How then do we stop democracy becoming more than a 'myth and a shibboleth'? If the law has not been capable of providing answers then I would suggest looking outside our conventional legal institutions, indeed turning to the very source of the control paradox, that is, the risk analysis paradigm. As I shall examine over the following chapters, this is the course that is being taken by modern legislatures.

Risk Communication. The third pillar – the other two being risk assessment and risk management [see 7.2] – of the risk analysis paradigm is entitled 'risk communication'. It is a relatively new device, not expressly part of the Red Book model [see 7.1]. Rather it was incorporated later in order to assuage public

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[3] *ibid.*

concerns about the 'closed shop' of risk assessment. Originally envisioned as a process to make risk analysis more transparent, it has gradually evolved into a mechanism to ensure that the public becomes more involved in risk analysis.

The latter half of this thesis will examine the rise of risk communication, its movement into risk analysis law and policy internationally and the concomitant movement towards deliberative risk governance. It will consider how and if risk communication can serve as an institutional mechanism to tip the balance back towards the democratic basis for regulating. Thus, the following discussion examines the movement towards *re-involving* the public in risk governance, because, to borrow again from Justice Kirby:

> [i]t is for our society to decide whether there is an alternative or whether the dilemmas posed by modern science and technology, particularly in the field of bioethics [and gene technology], are just too painful, too technical, complicated, sensitive and controversial for our institutors of government.[4]

11.1 APPROACHING RISK COMMUNICATION

Risk communication is an important part of any risk governance framework in a democracy, particularly where the subject matter is novel or technical. Involving the community in the decision making process validates governmental intervention in private activities. The modern risk communication approach allows for the education of both the community *and* decision makers, about risks and issues posed by new technologies. It allows risk governance to be malleable and react both to changes in the technology and to the community responses to those changes. Perhaps most importantly, it promotes trust in those empowered to make the final decision, and indeed in the risk governance process itself. Trust is integral to the efficiency and long-term success of a regulatory agency and the subject matter that it regulates. Without trust, the introduction of new technology into a democratic society will be resisted if not refused altogether.

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[4] *ibid*, pp 238-239.

Despite the above-mentioned benefits of risk communication, it must be recognised that pragmatically, the practice is as imprecise as the idea of risk itself. Risk communication can be time and resource intensive. It can reveal more information than a company or government may wish released for a variety of commercial reasons. Many see it as inhibitory to development and commercialisation. Thus, in practice, risk communication has had a slow uptake. It has also been, and indeed continues to be, applied in various forms and to varying degrees. Whilst risk communication theory has evolved substantially, particularly over the last decade, risk communication practice often lags by comparison.

The following two chapters will examine the ongoing development of risk communication and why risk communication was not just seen as a 'good idea' but an absolute institutional necessity. This will be quite an in depth study of the history of this aspect of the risk analysis paradigm, not least because it is so fundamental to this thesis. I would also defend such an involved examination because, as I will reveal over the course of this discussion:

- risk communication practice is often driven by public anger at institutional actors, for failing to sufficiently attenuate risks and act in the public interest. Therefore risk communication is fundamentally part of the risk dilemma in the blame society;
- the development of risk communication policy often far outstrips risk communication practice. Thus, different institutional actors use of risk communication within risk analysis (corporate) or risk governance (government) frameworks is often several 'stages' behind best practice;
- failures to implement 'best practice' risk communication were one of the primary reasons for the introduction of the GTA;
- only by understanding why each stage of development of risk communication was absolutely necessary can we understand what risk communication practice should be avoided and what risk communication practice should be promoted; and

- understanding risk communication successes and failures will provide an insight into whether the GTA implements an effective, real and successful model of risk communication.

11.2 THE DEVELOPMENT OF 'RISK COMMUNICATION'

Risk communication can be defined variously, depending on: who is disseminating information; the nature of the information; and the audience it is being provided to. For instance, companies regularly employ risk communication strategies to convince the public that their goods are safe. Alternatively, a special interest group may employ similar tactics to warn the public against using certain goods. From a risk governance perspective, risk communication generally describes the interchange of information between agency and relevant parties. The Red Book [see 7.1.1], which made mention of the need for disclosure, did not go into any substantive detail as to how this was to occur. Indeed the term risk communication developed after that report was published. Like risk management before it, the process of risk communication was left to develop through experience and policy over the next several decades.

The seeds of risk communication policy can be found prior to the inception of the Red Book paradigm, in a much broader debate about transparency and openness in governmental decision making in general. This debate was, in very large part, a response to the rise of individualism of the 1960s and the social rights revolution that ensued. Accountability came to be seen as the linchpin of democracy as the population became 'receptive to ideologies which legitimated the criticism of subordinates of their superiors.'[5] In his 1964 paper 'The New Property' Charles Reich wrote:

> [e]ventually, those forms of largesse which are closely linked to status must be deemed to be held as of right … At the very least, it is time to reconsider theories under which new forms of wealth are regulated, and by which governmental power over them is measured. It is time to recognize [sic] that 'the public interest' is

[5] Douglas R, *Douglas and Jones's Administratie Law,* Federation Press 2002, p 49.

> all too often a reassuring platitude that covers up sharp clashes of conflicting values, and hides fundamental choices….We cannot safely entrust our … rights to the discretion [of Government]. We cannot permit any official or agency to pretend to sole knowledge of the public good. We cannot put the independence of any man … wholly in the power of other men.[6]

No longer were governance and Government perceived as one and the same. Instead, the Government was seen as an executor of properties and rights vested in it by the greater public. Thus, the role of Government was to redistribute and manage these properties in a responsible and accountable manner and in accordance to the public's wishes.

11.2.1 THE OPENING OF ADMINISTRATIVE LAW

While perhaps Reich expectation that the legal system would open itself entirely to public scrutiny, may have been overly optimistic, there was indeed a revision of the Westministerial process.[7] In Australia this took the form of what was later called the 'New Administrative Law', a package of Commonwealth Acts designed to open the public sector to greater transparency and accountability.[8] The *Ombudsman Act* 1976 (Cth) and *Freedom of Information Act* 1982 (Cth), in particular, emphasised the right of the public to open and transparent decision making.

The move to introduce accountability and transparency in the process of law making was reflected at the international level, albeit somewhat later than that of the domestic level. Several international treaties with direct relevance to human

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[6] Reich C, 'The New Property' (1964) *Yale Law Journal* **73**:787.

[7] see Commonwealth Administrative Review Committee (Kerr Committee) *Report No 144 of 1977*, Commonwealth of Australia (AGPS), Canberra, 1977.

[8] These included the: *Ombudsman Act* 1976 (Cth), *Freedom of Information Act* 1982 (Cth); *Administrative Decisions (Judicial Review) Act* 1977 (Cth); *Administrative Appeals Tribunal Act* 1975 (Cth).

health and safety have called for regulatory decision making to be accountable and participatory.[9]

Risk analysis did not become suddenly more democratic with the introduction of the 'new administrative law'. [10] Rather, as an ancillary process to that discipline, it was left to evolve by itself, with only the weight of the new public individualism to drive it towards a more accountable, transparent and participatory form of decision making. Subsequently, risk communication has developed slowly and infused itself (often unwelcomely) into the risk analysis paradigm. Furthermore, risk communication – a concept designed to allay public concerns and create trust – has actually served to create concerns among some scientists, industry and regulators over its potential to derogate from the efficiency of the risk assessment process itself or result in an 'erosion of science based decision making'[11] [see 11.4, 12.5, 17.2.1]. As a result, risk communication principles have, on the whole, remained vague and generalist in nature (the antithesis of a standardised risk assessment practice), because there has been a general reluctance among those in control of the process to make such principles a requisite part of risk analysis. Only recently can this truly be said to have changed, with risk communication evolving into a standardised and necessary component of Australian and international risk governance law.

11.2.2 RISK COMMUNICATION STAGES

The development of risk communication policy from a mere inference in the 'Red Book', to a standardised and independent pillar of the overall paradigm has been

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[9] These include the: Stockholm *Health Impact Assessment as part of Strategic Environmental Assessment Declaration,* (1972) ; *Rio Declaration* (1992); and *Aarhus Convention On Access To Information, Public Participation In Decision-Making And Access To Justice In Environmental Matters* (United Nations Economic Commission for Europe) 1998.

[10] The World Health Organisation (WHO) has recognised that such conventions have in effect been 'neglected' or that their implementation inadequate. World Health Organisation, *Health Impact Assessment As Part Of Strategic Environmental Assessment,* World Health Organisation, Regional Office for Europe, Rome, 2001 p 7.

[11] Tambling G, '*Gene Technology Bill* 2000… Second Reading', *Senate Hansard,* 8/11/2000, p 19369. see also Washer *op cit 4*.

described by William Leiss as having evolved over three sequential stages. These were:

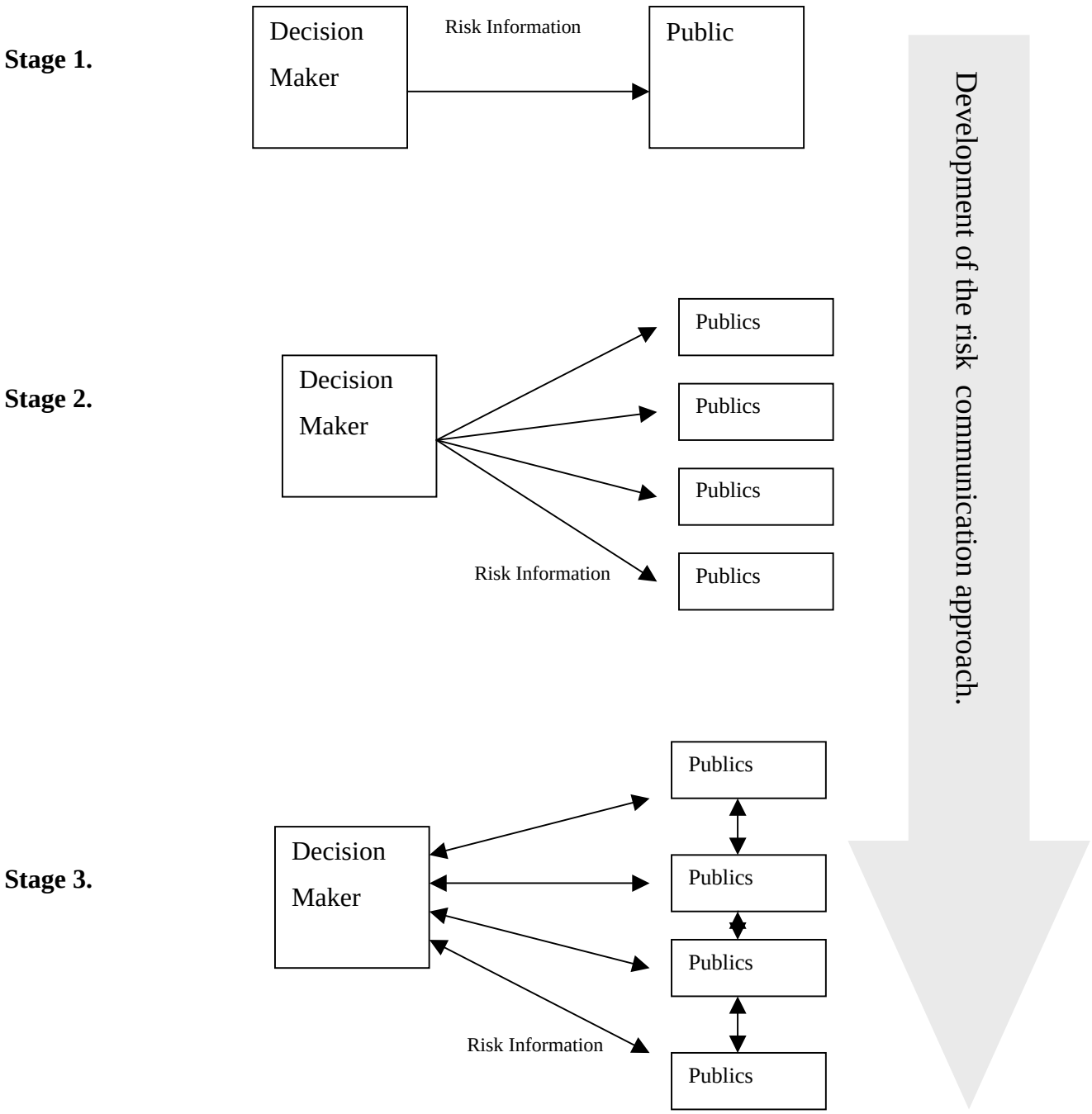
- simply informing the public that risk assessment and management decisions were right (unidirectional model);
- using different communication strategies for various sections of the public to convince each group the decision adopted was the best one (multidirectional model); and
- actively involving the community in the decision making process (deliberative model). [12]

Figure 4 (pg 314) reflects the development of risk communication policy, which will be discussed in the next chapter. As will be noted later, the pragmatic reality is that risk communication practice has not, in many instances, evolved at the same rate as risk communication policy. Initial approaches to gene technology risk communication practice have been more reflective of the two earlier stages referred to above. The effect of these strategies has influenced the final risk communication mechanisms within the GTA. Consequently, to better understand and evaluate the risk communication strategies that are adopted, or could be potentially adopted within the GTA, it is necessary to examine:

- the development of the modern risk communication approach;
- why the earlier approaches were considered incomplete; and
- the benefits of the modern risk communication approach to gene technology regulation.

[12] See Leiss [Leiss W, 'Risk Communication**:** Three Phases In The Evolution Of Risk Communication Practice' (1996) *The Annals of The American Academy of Political and Social Science* **545**:85], who argues that Risk communication developed over three *specific* phases to which he attributes dates. Within an international context there is less certainty on the actual dates as different countries, academics and international bodies were variously proactive and reactive in regards to altering their risk communication policies and laws.

Figure 4 [13]



[13] Model adapted from Leiss, *op cit* 12, and the following evolution of risk communication policy and practice.

Note, Stage 2 was originally described as an 'interactive' process. However this was more of an 'appearance' of interactivity [see (text)]. Hence the above diagram has the risk information message only travelling in one direction.

11.3 STAGE 1 : TELLING THE PUBLIC

As was noted above, there was a shift in public attitudes towards Government during the mid to late twentieth century. This shift had a major impact on the development of risk governance. Carson's famous 'Silent Spring', written in 1962,[14] brought worldwide attention to the impact that human activity was having on the environment and on human health.[15] The book, although academic in nature, was taken up by the general populace and had a profound effect on the way ordinary citizens considered the world around them.[16] It struck a chord with a public already scared about the implications of the nuclear arms race and revelations about the side-effects of thalidomide.[17]

Whilst *Silent Spring* concentrated on the problems of pesticides, the book's impacts were much broader, instigating an attitudinal re-evaluation of much of modern technology, the uses to which it was put and the impacts it presented to human health and the environment. Increasing sections of the community (at least in the developed world) were no longer willing to accept *carte blanche*, risk management decisions, and there were an increasing number of objectors to industrial activity. *Silent Spring* also focused the existing dissatisfaction about nuclear power and gave a more unified voice to objectors of that technology.

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[14] Carson R, *Silent Spring*, Riverside Press, Cambridge, 1962.

[15] Gottlieb R, *Forcing the Spring*, Island Press, Washington, 1993, pp 19-35; Wiess E.B., 'Trade And Environment: Environment And Trade As Partners In Sustainable Development' (1992) *American Journal of International Law* **86**:728; Brown P, 'Preface', (2002) *The Annals of The American Academy of Political and Social Science* **584**:7 ; Manus P.M., 'The Owl, The Indian, The Feminist, And The Brother: Environmentalism Encounters The Social Justice Movements' *Environmental Affairs Law Review*, **23:**249-299.

[16] "Silent Spring's impact was immediate: President Kennedy ordered an investigation into the impact of pesticides, and the book was debated and discussed in venues ranging from New England town meetings to the U.S. Congress to the British House of Lords. The Book of the Month Club printed 150,000 copies, and Carson was widely interviewed on television." Sherman S, 'Environmental Truth' (2001) *Columbia Journalism Review* 4:**14**:53.

[17] "Following on the heels of the thalidomide debacle and recent publicity about the danger of nuclear fallout, Silent Spring reached an audience already anxious about the brave new world of chemicals and atomic energy." Smith M.B, 'Silence, Miss Carson! Science, Gender, And The Reception Of Silent Spring' (2001) *Feminist Studies* 3:**27**:733.

Government and industry (particularly in the US) struggled to gain public acceptance for the emerging nuclear industry, despite the fact that the technology posed a cheap and efficient solution to energy demands. How to deal with the new public preoccupation with risk became a major issue for both government and industry.

Government and industry (particularly in the United States) struggled to gain public acceptance for the emerging nuclear industry, despite the fact that the technology posed a cheap and efficient solution to energy demands. How to deal with the new public preoccupation with risk became a major issue for both government and industry.

The public reaction to technological risk – previously a minor consideration in risk analysis – now dominated the agenda. Risk managers were convinced that their decisions were the right ones, but the public were often sceptical. Thus, risk managers in government and in industry undertook what Slovic calls, a 'desperate search for salvation', in order to determine how to deal with the public backlash to risk decisions.[18] Their answer was the process that was to become 'risk communication'.[19]

11.3.1 STARR'S ACCEPTABILITY SCALE

The seminal work on risk communication was Starr's 1969 paper in *Science* entitled 'Social Benefit Versus Scientific Risk'.[20] In that paper Starr sought to determine, in relation to the development of new technologies, 'how safe is safe enough?'. He formulated an 'acceptability scale' which could be used to predict future public responses to technological developments. This formula was premised on the assumption that a case history of new technologies could provide

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[18] Slovic P 'Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield', (1997) *University of Chicago Legal Forum* **59:**61.

[19] *ibid.*

[20] Starr C, 'Social Benefit Versus Technological Risk' (1969) *Science* , **165**:1232-123.

a basis upon which to construct normative models of future outcomes.[21] Using existing data Starr extrapolated a monetary value from the social benefit of technological activities by producing a cost (fatalities per person) benefit (social, economic) scale for voluntary and involuntary hazards. From this scale he arrived at several conclusions about public risk acceptance.

Starr found that participants in voluntary activities, such as transportation or sport, suffered mortality rates up to a thousand times higher than involuntary activities such as natural disasters or accidents from electrical power generation. Hence he concluded that voluntary risks were a thousand times more 'acceptable' to the public than were involuntary ones.[22] He also argued that the awareness of risk has a strong and direct influence on acceptability. Moreover, acceptability of risk was, according to his sliding scale, approximately relative to perceived benefit taken to the third power.

Risk 'Perception' vs Numeric Risk. Starr's work was pivotal because it showed that risk perception often did not accord to numerical risk. Subsequent studies into the perception of risk established additional factors that may affect the 'acceptability scale'. For instance, the perception of risks from novel technologies, such as nuclear power, would be over inflated, particularly where the effects of those technologies were unknown or would be delayed.[23] Fischhoff *et al* concluded in a 1978 study that risk perception can often have little to do with *actual* fatality or morbidity rates.[24] Rather, their survey showed that the public

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[21] There were two fundamental premises here. Firstly historical records of accidental deaths from new technologies were sufficient to quantify the probability of future deaths from all new technology. Secondly historical preferences and social costs of populations were taken to be static enough to produce predictive models of future social preference and costs.

[22] Starr's analysis has been used to explain why different populations within the same geographical area have different acceptance levels for risks. For instance, relatively affluent citizens tend to be more mobile, or at least capable of moving from one place to another. Hence they may perceive the placement of a hazardous industry such as a nuclear power plant within their vicinity as 'voluntary' as they have the option of moving to another locale. On the other hand, economically disadvantaged citizens who are unable to 'escape' would perceive the risk to be involuntary and thus have a much lower acceptability threshold than their wealthy neighbours Rasmussen N C. 'The Application Of Probabilistic Risk Assessment Techniques To Energy Technologies' (1981) *Annual Review of Energy*, **6**:123-138. :

[23] *ibid.*

[24] Fischoff B, *et al*, 'How Safe is Safe Enough?' (1978) *Policy Sciences* **9**:127-152.

tends to consider anything which is new, imposed upon them, unfamiliar, and *beyond their control* to be of 'high risk' regardless of scientific evidence to the contrary.[25] Moreover, the effect of everything from media hype to general ignorance can lead individuals to over or under estimate the actual likelihood of risk of an activity.[26]

This is not to say that people mistake the level of risk. In fact while they may be mistaken about the magnitude, individuals can generally rank various risks in a relatively accurate manner.[27] However, people could be said to be 'incorrect' about the seriousness of each risk albeit from the 'expert' standpoint.[28] Many in the community may realise that a nuclear power station poses an extremely low potential for exploding or leaking, but this does not diminish how serious a risk they believe its existence poses.

Using Risk Communication to Expound the Numeric Risk. The 'acceptability scale' approach was predicated on two fundamental assumptions.[29] First, there was a causal relationship between perception, or indeed ignorance, of risk and the acceptance of that risk.[30] Second, methods could be introduced to minimise the ignorance that led to over inflated risk perception, pushing the subject matter up the acceptability scale.[31] Hence, risk communication was formed as a method of

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[25] *ibid.*

[26] Slovic P, Fischhoff B, Lichtenstein S, *Uncertainty: Heuristics and Biases*, Cambridge University Press, Cambridge, UK. 1982, pp. 463-489.

[27] *ibid.*

[28] "technical experts are profoundly puzzled, frustrated, and disturbed by public and political opposition that many of them consider to be based on irrationality and ignorance" Slovic P, Flynn J, Layman M, 'Perceived Risk, Trust, and the Politics of Nuclear Waste', (1991) *Science* **254:**1603.

[29] See generally Starr C, Whipple C, 'Risks of Risk Decisions', (1980) *Science*, **298**:1115.

[30] "society's apparent aversion to involuntary risks may be mostly an illusion" Slovic P *et al*, 'Facts and Fears: Understanding Perceived Risk', in Schwing R, Albers W, eds. *Societal Risk Management*, Plenum Press, New York, 1980 p 181.

[31] McColl E, Bennett C, 'A People-Centered Concept of Society-Wide Risk Management' in Stephen R, *ed. Environmental Health Risks: Assessment and Management*, University of Waterloo Press, Waterloo, 1987, p. 272.

influencing the risk perception of the general public and increasing the acceptability of activities which government or industry wished to promote.[32]

It was originally envisaged that 'ignorant' perceptions of risk could be adequately overcome by educating the public to the 'real' risks. Thus, the most powerful weapon in the risk communicator's arsenal was the statistical and analytical probability of risk, gained from scientific risk assessment.[33] Any 'legitimate' concerns that could not be allayed by risk data were 'intuitive' and could be adequately dealt with by 'political resolution'.[34] The political solution to dealing with intuitive risks was often to 'frame' the information in a way which dealt with the underlying reasons for 'misapprehension' of the 'real risk'.[35] By this rationale, framing risks as 'voluntary' or 'substantially equivalent' to existing risks, will foster increase acceptance of them.[36]

11.3.2 AN INCOMPLETE PICTURE OF RISK PERCEPTION

Starr's paper, while groundbreaking, came to be criticised as an incomplete picture of the social and political factors that contribute to public acceptance of risks. In particular, the reductionist cost benefit approach was attacked for being inadequate.[37] Ironically, Starr concluded that nuclear power plants, which are designed to be economically efficient, had lower levels of risk than are normally 'accepted' for the generation of power and therefore would become 'acceptable'. In hindsight, it is easy to see that using a mortality rate versus social benefit formula may not result in an entirely accurate picture of public sentiment.

Not only did the cost benefit analysis present an inaccurate picture, it was also

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[32] Fischoff B, "Risk Perception and Risk Communication unplugged: Twenty Years of Process," (1995) *Risk Analysis*, **15**:137-45.

[33] *ibid.* at 1116.

[34] *ibid.*

[35] Slovic P, *et al*, 'Behavioral Decision Theory Perspectives on Risk and Safety', (1984) *Acta Psychologica* **56**:185.

[36] Hadden G, *Citizen's Right to Know: Risk Communication and Public Policy*, Westview Press, Westview, 1989, at 139.

[37] Misa T, ElBaz S, 'Technological Risk and Society: The Interdisciplinary Literature,' (1991) *Research in Philosophy and Technology* **11**:301-386.

seen by some as being an economically driven attempt to justify unpopular activities.[38] The result, according to some, was a decline in the 'impetus for public decision-making' as large components of the assessment and management process were placed in the hands of 'experts' and officials.[39] Hence the purely numerical approach to determining risk acceptance not only failed to convince many that risk decisions were correct, but it also engendered distrust and dissatisfaction about the transparency of the whole process.

> Risk communication cannot be a one-way communication and still be effective. Community involvement in either directly reducing risks or public participation at the risk assessment level is needed to calm community fears. Overall, in order to build trust in government regulation of risks, government is going to have to focus on reducing, if not eliminating risks, instead of on calculating the amount of harm that is 'acceptable'.[40]

11.4 STAGE 2 : TALKING TO THE PUBLIC

Early risk communication strategy was not as successful as predicted. Whilst some in the community were influenced by risk data, others were less receptive.[41] What became clear is that there tends to be a general inconsistency between various individual, social, peer and political group perceptions of the seriousness of risks.[42] The perception of risk is intrinsically related to whom is judging it.

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[38] *ibid. ;* Lyndon M, 'Risk Assessment, Risk Communication and Legitimacy', (1989) *Colombia Journal of Environmental Law* **14**:289.

[39] Fiorino M, 'Environmental Risk and Democratic Process: A Critical Review', (1989) *Columbia Environmental Law Journal,* **14**:529-30.

[40] Bunting K, 'Risk Assessment and Environmental Justice: A Critique of the Current Legal Framework and Suggestions for the Future', (1995) *Buffalo Environmental Law Journal* **3**:140-141.

[41] Vlek C, Stallen P, 'Rational and Personal Aspects of Risk' (1981) *Acta Psychologique* **45**:257-300.

[42] Hence, in a famous study by Slovic, college students and a league of women voters ranked nuclear power the most serious risk out of thirty different activities, whereas active members of a social club ranked it eighth. Experts on the other hand ranked it twentieth. Slovic P, 'Perception of risk', (1987) *Science,* **236**:280-285.

11.4.1 MULTI-MESSAGE COMMUNICATION

How to deal with the divergent views about the seriousness of risk proved a significant problem for decision makers. In such an environment, universal acceptance was unattainable so long as community members held so many different views. 'Expert opinion' was one of several viewpoints. Whilst it may have held weight with some of the population, it would not, and could not, prove the decisive factor in ensuring public acceptance.[43] During the 1980s a shift in academic focus from a single risk message to a multi-message one occurred, in recognition of the way different groups perceived risk.[44] In 1989, the US National Academy of Science and National Research Council (NAS-NRC) [see 7.1.1] enshrined these concepts in a new model of risk communication which it defined as:

> An interactive process of exchange of information and opinion among individuals, groups and institutions. It involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management.[45]

Still Unidirectional. In principle, multi-message risk communication was intended to 'establish trust by listening to the public and addressing the reasons for mistrust'.[46] This, it was hoped, would placate 'fears' and 'enable individuals and

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[43] Leiss W, Krewski D, 'Risk Communication: Theory and Practice' in Leiss W, ed, *Problems and Problems in Risk Communication*, University of Waterloo Press, Waterloo, 1989, pp. 89-112.

[44] Vlek C, Stallen P, 'Rational and Personal Aspects of Risk' (1981) *Acta Psychologique* **45**:257-300; Douglas M, *Risk Acceptability According to the Social Sciences*, Russel Sage, New York, 1986; Sandman P, 'Risk Communication: Facing Public Outrage' (1987) *EPA Journal*, 9:**13**:21-22. , Slovic P 'Perceptions of risk' (1987) *Science* **236**:280-285; Otway H, Wynne B , 'Risk Communication: Paradigm and Paradox', (1989) *Risk Analysis* **9**:141.

[45] National Research Council, *Improving Risk Communication*, Report of the Committee on Risk Perception and Communication, National Academy Press, Washington, D.C. 1989.

[46] Kasperson R, Golding D, Tuler S, 'Social Distrust as a Factor in Siting Hazardous Facilities and Communicating Risks' (1993) *Journal of Social Issues*, 4:**48**:161-187.

groups to better cope with technology'.[47] Note that the assumption was that public concerns could be overcome by conveying the 'right' message.

Despite the realisation that the public interest was an important element in risk governance, risk communication theory remained fixed in the belief that risk perceptions derived from ignorance or 'illegitimate' concerns.[48] The result was that, in practice, multi-message risk communication remained, for the most part, a one-way model, albeit in a diversified form. Whilst terms such as 'interactive', 'listening' and 'addressing' were used, in practice a decision had already been made by the time the decision maker 'interacted' with the public.[49] The post-decision multi-message communication was tailored to allay 'the reasons for mistrust' in respect of the decision made, rather than *actually arriving at a decision* based on those reasons.

The practical application of multi-message risk communication continued to be 'political resolution', which, according to Leiss, was very much an exercise in customer relations.[50] He argues that the process 'remained incomplete because the key ingredient of successful persuasive communication, trust, cannot be

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[47] Kasperson R, 'Six Propositions on Public Participation and Their Relevance for Risk Communication' (1986) *Risk Analysis* **275**:6.

[48] Slovic P, Flynn J, Layman M, 'Perceived Risk, Trust, and the Politics of Nuclear Waste' (1991) *Science* **254:**1603 ; Cross F, 'Comparative Risk Analysis And Public Policy: Iv. Making Risk Policy In The Face Of Expert/Public Conflicts: The Subtle Vices Behind Environmental Values' (1997) *Duke Environmental Law and Policy Forum,* **8**:151-155; Thompson P, 'Risk Objectivism and Risk Subjectivism: When Are Risks Real?' (1990) *Risk: Issues In Health and Safety* 1:**3**:22.

[49] Because of the need to coordinate a more diverse constituency, risk communication moved from the risk assessment phase and was taken up by risk managers. Information was presented to risk managers who interpreted it. Individual strategies were adopted to communicate this data to divergent sectors of society. Fischoff B 'Managing Risk Perceptions' (1985) *Issues in Science and Technology,* **2**:83-96; Leiss W, 'Down and Dirty; The Use and Abuse of Public Trust in Risk Communication' (1995) *Risk Analysis,* **15**:685-92.

[50] Leiss W, 'Risk Communication**:** Three Phases In The Evolution Of Risk Communication Practice' (1996) *The Annals of The American Academy of Political and Social Science,* **545**:85; The NAS-NRC concluded in their 1989 Report that "it is mistaken to expect improved risk communication to always reduce conflict and smooth risk management . . . . But even though good risk communication cannot always be expected to improve a situation, poor risk communication will nearly always make it worse." National Research Council, *Improving Risk Communication,* Report of the Committee on Risk Perception and Communication, National Academy Press, Washington, D.C, 1989, p 3.

manufactured by the use of techniques alone, no matter how artful the practitioners are'.[51]

11.5 STAGE 3 - A DIALOGUE

Reinterpreting risk data for individual groups in a multi-message approach had done little to increase trust.[52] Government, industry and academics reported a lack of trust in risk decisions, despite the advances in risk communication theory and practice. Rather than placate concerns, public dissatisfaction grew, counter industrial lobby groups formed and issues such as the environment and public safety became dominant political issues.[53] This accords with the rise of the risk society described by Ulrich Beck and as I have stated previously the blame society [see 5.2].

11.5.1 FOCUSING ON TRUST

The rise of the blame society caused major complications for risk managers, and there was a struggle to regain public trust. There had been an almost institutionalised acceptance among members of government that, so long as decisions were being made in a democratic system (responsible government) and people were being informed about those decisions (administrative transparency), the electorate would trust the decisions were right. [54] This proved not to be the case.[55]

Several studies into why the public did not trust officials were undertaken in the 1990s.[56] Many of these studies focused on the failures of risk assessment and risk

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[51] Leiss *op cit 12,* p 91.

[52] Otway H, Wynne B , 'Risk Communication: Paradigm and Paradox', (1989) *Risk Analysis* **9**:141.

[53] Beck U**,** *Risk Society: Towards a New Modernity,* Sage, London, p 206.

[54] Slovic P 'Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield', (1997) *University of Chicago Legal Forum* **59:**61.

[55] *ibid.*

[56] See Frewer L.J, *et al*., 'What Determines Trust in Information About Food-Related Risks? Underlying Psychological Constructs' (1996) *Risk Analysis* **16**:473 ; Slovic P, 'Perceived Risk, Trust, and Democracy'

management. Some argued that the public had come to mistrust government and corporate decision making so much, that the inception of risk communication appeared a mere façade.[57] Others posited that continuing failures of risk managers to properly attenuate risks created an environment of 'recreancy'.[58] Recreancy, it was argued, came about from increased levels of interdependence within society, created by an increasingly marked division of labour. This in turn fostered an environment where there was a perceived 'failure of institutional actors to carry out their responsibilities with the degree of vigour necessary to merit the societal trust they enjoy'.[59] It was further suggested that terms such as risk assessment created too high an expectation upon decision-makers because they were doomed to prove fallible.[60]

Risk Communication And Trust. Risk communication did not escape critique either, with some arguing the practices adopted by risk managers compounded public distrust rather than easing it.[61] Perhaps the most common concern was that

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(1993) Risk Analysis **13**:675 ; Barling D, *et al*, 'The Social Aspects Of Food Biotechnology: A European View' (1997) *Environmental Toxicology and Pharmacology***, 7:**85-93.

[57] Slovic P, MacGregor D. M, *The Social Context Of Risk Communication*, Decision Research Report No. 02-06, Oregon, 1994.

[58] Freudenberg R, 'Risk and Recreancy' (1993) *Social Forces* **71**:909; 'in essence, the failure of an expert, or for that matter a specialized organisation, to do the job that is required. The word comes from the Latin roots re- (back) and credere (to entrust), and the technical meaning is analogous to one of the dictionary meanings, involving a retrogression or failure to follow through on a duty or a trust. The term is unfamiliar to most, but there is a simple reason for its use: we need a specialized word if we are to refer to behaviours of institutions or organisations as well as of individuals and, importantly, if the focus of attention is to be on actual behaviours. One indication of the societal importance of trustworthiness, in fact, is that virtually all of the common words having comparable meanings have come, over time, to take on a heavily negative set of connotations. To say that a technical specialist is responsible, competent, or trustworthy, for example, is to offer at least a mild compliment, but to accuse that same person of being irresponsible, incompetent, or of having shown a betrayal of trust, is to make a very serious charge indeed. While "recreancy" may not be an everyday term, the need for it grows quite directly out of the necessity of avoiding the emotional and/or legal connotations of the available alternatives.' Freudenburg R, 'Uncertainty And Risk Assessment: Risky Thinking: Irrational Fears About Risk and Society', (1996) *The Annals of The American Academy of Political and Social Science* **545**:44.

[59] *ibid.*

[60] Instead terms such as 'risk estimation' were recommended as more apt. Corvellow V, Merkhofer M, *Risk Asssessment Methods*, Plenum Press, New York, 19994.

[61] Slovic P, 'Perceived Risk, Trust, and Democracy' (1993) *Risk Analysis* **13**:675-82 ; Slovic P, MacGregor D. M., 'The social context of risk communication', Decision Research Report No. 02-06, Oregon, 1994.

institutional actors had failed to adequately and *actually* involve the public in making risk decisions.[62] In many cases, risk managers assumed the public was ignorant, and could be educated to the true nature of risk.[63] Whilst in many cases this may be true, such a presumption fails to recognise that risk is neither value-neutral nor absolutely quantifiable. Some public concerns are genuine, or relate to risks which are not identified by the ordinary risk assessment process [see 8.2]. Even where concerns are without scientific basis, merely telling people they are ignorant is unlikely to elicit support for the course of action adopted. To say to someone, 'this is the decision we have arrived at and this is why it is good for you', will more often than not, be counterproductive.

Stage 3 was marked by a realisation that risk decisions needed to be made with the participation of those affected by the risk. It differed from stage 2, in that the emphasis was no longer on making a decision and then telling the public why they should overcome their fears. Rather, Stage 3 was about creating dialogues in which the decision maker *and* the public informed each other as to what the best decision should be. It was intended to be about opening *real* channels of communication between the various 'organisational actors',[64] including the community, industry and government throughout the risk analysis process, rather than after it. Jasanoff *et al* explain the basis of this policy as follows.

> Science and technology cannot thrive in democratic societies unless they are backed by strong public support.
>
> ... the problem is ... in matching peoples actual needs and preferences. Concepts such as "just-in-time" science instruction, continuing education, and other forms of two way communication seem more promising in this context than inflexible tests of scientific literacy. In two-way exchanges, the ability of scientists to understand the public

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[62] Simpson A *Integrating Public and Scientific Judgments into a Tool Kit for Managing Food-Related Risks, Stage II: Development of the Software*, ERAU Research Report No. 19, University of East Anglia, Norwich, 1993.

[63] Slovic P, MacGregor D. M., *The Social Context Of Risk Communication*, Decision Research Report No. 02-06, Eugene, OR: 1994, p 9.

[64] Leiss, *op cit* 12, p 91.

> becomes at least as much a concern as the public's understanding of science.[65]

11.5.2 AGENDA 21 AND PARTICIPATORY RISK ANALYSIS

The international community, at the 1992 Rio Earth Summit, undertook the first real discussion of the need for transparent, integrated and deliberative decision making with respect to health and environment. Agenda 21 was one of three major documents released at that summit and is most relevant to this discussion because it focuses on implementing global strategies at a local level by including local communities, stakeholders and industry in decision making processes and utilising their knowledge to promote solutions at a local level.[66] Agenda 21 was adopted by 178 Nations,[67] including Australia.[68] Paragraph 23.1 of the Agenda states:

> [o]ne of the fundamental prerequisites for the achievement of sustainable development is broad public participation in decision-making. Furthermore, in the more specific context of environment and development, the need for new forms of participation has emerged. This includes the need of individuals, groups and organisations to participate in environmental impact assessment procedures and to know about and participate in decisions, particularly those which potentially affect the communities in which they live and work. Individuals, groups and organisations should have access to information relevant to environment and development held by national authorities, including information on products and activities that have or are

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[65] Jasanoff S; Colwell R ; Dresselhaus MS; Goldman RD; *et al* 'Conversations With the Community: AAAS at the Millennium' (1997) *Science* 5346:**278**:2067.

[66] *Agenda 21* (United Nations Division for Sustainable Development) 1993 [herein Agenda 21], SECTION III. Including women, children, indigenous peoples, NGOs, local authorities, workers and trade unions, business and industry, scientific and technology and farmers.

[67] Information on Agenda 21 can be found on the UNEP website : <http://www.un.org/esa/sustdev/agenda21.htm> (11/10/02).

[68] Cotter B, Hannan K, *Our Community Our Future: A Guide to Local Agenda 21,* Environs Australia Report, Commonwealth of Australia, Canberra, 1999.

> likely to have a significant impact on the environment, and information on environmental protection measures.

To better facilitate the process of decision-making, Agenda 21 promotes the need for education, the raising of public awareness and training, in all areas covered by the Agenda.[69] It promotes the use of science as central to decision making practices but emphasises that 'communication is required among scientists, decision makers, and the general public.'[70] 'Risk evaluation' should, according to the Agenda, be 'adaptive and responsive' and be carried out via 'transparent, user friendly' methodologies.[71]

The Agenda recommended the further development of risk assessment and risk management process with respect to gene technology.[72] Whilst it never used the phrase 'risk communication', it spoke of the need to make gene technology risk assessment and risk management more transparent, inclusionary, integrative and informed, ensuring the 'widest possible public participation'.[73] Paragraph 16.29 of the Agenda states,

> There is a need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. Only when adequate and transparent safety and border-control procedures are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology.[74]

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[69] para. 36.1,Agenda 21.

[70] para 35.5, Agenda 21.

[71] para 35.7, Agenda 21.

[72] para.16.32 (b), Agenda 21.

[73] "The aim of this programme area is to ensure safety in biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management, with particular reference to health and environmental considerations, including *the widest possible public participation* and taking account of ethical considerations." Emphasis added. para. 16.30, Agenda 21.

[74] para 16.29, Agenda 21.

The development of risk management principles identified in Agenda 21, included the need to educate the public and key decision makers to the benefits and risks of gene technology along with the promotion of ethical considerations.[75] It recommended that this development be led by: all levels of Government; international and regional organizations; the private sector; non-governmental organisations; academic; and scientific institutions.[76]

Agenda 21 is an important foundation document which sets out decision-making principles the international community has agreed to implement.[77] These principles set the cornerstone of the modern risk communication approach. They may be summarised as:

- *analytic*, recognising the need for methodological risk assessment methodologies to inform the communication process whilst simultaneously recognising the value of local and sectional knowledge to the analysis of risk;
- *multi-message,* requiring that technical information is explained adequately to concerned parties in a manner accordant to their expertise in the subject matter;
- *deliberative,* recognising the need for open and informed discourse over the implementation of new technologies. Agenda 21 obliged governments to inform the public of risks and simultaneously allow the public to inform decision makers of their own concerns; and
- *integrative,* recognising the need for information flows throughout the entire risk analysis process, during risk assessment and risk management.

Agenda 21 in a Risk Analysis Context. The 'integrative' multi directional approach has been well received in academic risk analysis dissertation. In 1993 Soby, Simpson and Ives, presented a model in which risk communication could be

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[75] paras.16.4(b), 16.33, 16.39(a)iii,16.40(b), Agenda 21.

[76] para.16.40, Agenda 21.

[77] United Nations General Assembly Resolution, *Programme for the Further Implementation of Agenda 21*,A/RES/S-192 19 September 1997 ; Report of the Secretary-General of the Economic and Social Council, *Implementing Agenda 21***,** Commission on Sustainable Development Rept (E/CN.17/2002/PC.2/7), New York, 2001.

integrated into the overall paradigm.[78] They recommended the adoption of risk communication throughout the entire process of risk assessment and risk management. This system allowed the community and stakeholders to input and participate in the decision making process itself.

11.6 ACCEPTANCE OF PARTICIPATORY RISK COMMUNICATION (STAGE 3) IN AUSTRALIA : THE NHMRC REPORT

Australia was highly responsive to the international move towards more participatory risk governance. In 1994, the Australian National Health and Medical Research Council released a report entitled '*National Framework For Environmental And Health Impact Assessment*' (the NHMRC report). That report expressly recommended a multi-directional risk communication model and a need to integrate 'technical and value-driven considerations' into risk governance.[79] According to the report, both the public *and* scientists required risk education. The public required a better understanding of scientific and technical aspects of risk. Scientists required a better understanding of the basis and legitimacy of public concern.

The NHMRC report concluded that public concerns should form part of the risk analysis process from an 'early' stage.[80] The implication being that such interaction should occur during risk assessment. Public input into the risk management process (including approvals, licenses and plans) was also seen as necessary.[81] Finally, the public were seen as having a role in continued monitoring of facilities.[82]

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[78] Soby B.A, Simpson A.C.D, Ives D.P, *Integrating Public and Scientific Judgments into a Tool Kit for Managing Food-Related Risks* ERAU Research Report No. 16, Centre for Environmental and Risk Management, University of East Anglia, UK. 125, 1993 ; Simpson, A, *Integrating Public an Scientific Judgments into A Tool Kit for Managing Food-Related Risks, Stage 2,* ERAU Research Report No. 19, Centre for Environmental and Risk Management, University of East Anglia, UK,1993.

[79] National Health and Medical Research Council, *National Framework For Environmental And Health Impact Assessment,* Commonwealth Department of Human Services and Health, 1994, para 5.2.1.

[80] *ibid.* Although it did not specifically state at what stage of the risk analysis deliberation should begin.

[81] *ibid.* 5.3.

[82] *ibid.*

The NHMRC report constituted a real movement towards integrative multi-directional risk communication. Nevertheless, it could not be said to have actually recommended a regulatory 'model' *per se*. Rather, it set out general principles which would facilitate better trust, transparency and public involvement in the regulatory process and risk decisions. The NHMRC did, however, recommend that 'structural mechanisms' be established to ensure such principles were actualised, especially in relation to less powerful groups such as consumers.[83]

11.7 ACCEPTANCE OF PARTICIPATORY RISK COMMUNICATION (STAGE 3) INTERNATIONALLY

The need to adopt better structural mechanisms was also recognised at the international level during the 22nd Session of the *Codex Alimentarius Commission* [see 7.1.3], held in Rome 1995. The Commission resolved to encourage governments to amend their approaches to risk communication to include explicit reference to consumers.[84] They established a new definition of risk communication as being:

> an interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.[85]

This definition was left open so as to capacitate continuing developments in the 'science of risk analysis and as a result of efforts to harmonize similar definitions across various disciplines'.[86]

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[83] *ibid.* 5.2.1

[84] Secretariat of the Joint FAO/WHO Food Standards Programme, *Report On The Financial Situation Of The Joint FAO/WHO Food Standards Programme For 1994/95 AND 1996/97,* Report) ALINORM 95/5 and ALINORM 95/5), World Health Organisation, Rome, 1998 ; also Joint FAO/WHO Expert Consultation Group, *Application of Risk Analysis to Food Standards Issues*, Report (WHO/FNU/FOS/95.3), FAO/WHO Expert Consultation Group, Geneva, Switzerland, 13-17 March 1995.

[85] Codex Alimentarius Commission, *Procedural Manual* 10th Ed., World Health Organisation Rome, 1997

[86] *ibid.*

11.7.1 THE 'ORANGE BOOK'

In 1996 the US NAS-NRC followed up the 'Red Book' with an 'Orange Book' (again, imaginatively named for its cover) report on risk characterisation and risk communication. The Orange Book was a conscious effort to extend the 'Red Book' paradigm, so as to engage stakeholders in the overall risk governance process.[87] The Committee recommended the merger of scientific analytical characterisation of risk and uncertainty with formal stakeholder deliberations at all stages of the process.

This model shifted the Red Book paradigm [see 7.1.1] towards an integrated, analytic-deliberative form of risk analysis (herein referred to as the 'participatory model'). Such a process was seen as necessary to foster transparency, trust and increased public knowledge of hazards.

The Orange Book, like its predecessor, was an extraordinarily important document and influenced the development of the risk communication paradigm. This is particularly true in the United States and because of that Countries influence internationally, on international agreements such as the WTO. Nevertheless, it is worth noting here that Australian NHMRC report played a much greater influence on later domestic developments, discussed later (specifically the Australian Commonwealth National Health Partnership Guidelines [see 12.2]), than the Orange Book. Ultimately it has been a more contemporary evolution and maturation of domestic law and policy that has shaped the form of risk analysis and risk communication within the GTA. Thus I have opted to discuss the participatory model in relation to the Australian approach below, rather than that set out within the US Orange Book.

11.8 CONCLUSION

The above study examined how the transformation of risk analysis from a primarily technical and expert oriented enterprise into a more participatory and

deliberative process. Those in charge of novel technology did not undertake this development in a wholly willing manner. Rather, it was compelled in response to a new public attitude of distrust in decision makers to adequately make public risk decisions in the absence of public input.

Thus, we see the rise of the blame society and the struggle to capacitate it by ensuring that technology is controlled in a manner accordant to the public interest. It is also evidence of the fact that the greater community is genuinely concerned and genuinely interested about the risk governance process. They wish to be involved in deciding, as Justice Kirby emphasises 'whether the dilemmas of modern science and technology … are just too painful, technical, complicated, sensitive and controversial for our institutions of government'.[88] Subsequently, risk governance must incorporate genuine processes for public involvement in decision making. Only then can the public truly trust the decisions of risk assessors and risk managers.

The next chapter will examine how the current deliberative stage 3 risk communication process has begun to be taken up by the law, so that it rejoins the new administrative law, to which it was once ancillary, in a more powerful, genuinely deliberative process. This I will argue, has moved risk communication into a new stage, one in which the philosophy of risk communication is put into practice, thereby gaining real process legitimacy.

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[87] National Research Council (US). *Understanding Risk: Informing Decisions In A Democratic Society*. Washington DC: National Research Council, National Academy Press, 1996.

[88] Kirby *op cit* 1. p 239.

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FROM COMMUNICATION TO DELIBERATIVE RISK GOVERNANCE

The first three stages of risk communication were generally 'best practice' guidelines or recommended 'models', adopted by institutions or regulatory agencies where they saw fit. The documents which promulgated risk communication policy were at best 'soft law', having little binding force upon risk managers or regulatory agencies. For instance, the US National Research Council of the National Academy of Science (US NAS-NRC) – which has tended to drive the development of risk communication internationally – is at best a reference guide in Australia; it carries no real legal weight. More relevant to domestic regulation is Agenda 21. Nevertheless, whilst being an important undertaking, it is not, nor purports to be, binding international law.

Perhaps the strongest Australian stage 3 document is the 1994 National Health and Medical Research Council report, '*National Framework For Environmental And Health Impact Assessment*' (the NHMRC Report [see 11.7]), which – being an Australian set of guidelines, by the peak national health body of this country – has regional and political influence. However, as a report it cannot be seen to have any real legal authority. Indeed, the NHMRC report is really just a set of guidelines for 'best practice' risk governance. Moreover, as has been discussed previously [see 11.7], the report did not attempt to spell out any set practices. Rather, it sought to establish a set of principles, which, it was hoped, would

eventually develop into actual legal mechanisms. Indeed, when Leiss first described stage 3 of risk communication in 1996, he noted:

> [a]t the moment, there is no code of good practice in this area that might provide some benchmarks for determining what is and what is not responsible risk communication, although I suspect that events during [stage 3] will lead in that direction.

Whilst stage 3 saw the development of participatory risk communication as 'good policy', the real challenge will be to effectively realise the principles of democratic risk governance within *actual legal frameworks*. This, in essence, marks a new stage in the development of the risk communication process. As Jasanoff questions:

> how can ideas of accountability be mapped onto well-entrenched relations between knowledge and power, or expertise and public policy? The time is ripe for seriously re-evaluating existing models and approaches. How have existing institutions conceptualized the roles of technical experts, decision-makers, and citizens with respect to the uses and applications of knowledge? How should these understandings be modified in response to three decades of research on the social dimensions of science? Can we respond to the demonstrated fallibility and incapacity of decision-making institutions, without abandoning hopes for improved health, safety, welfare, and social justice? Can we imagine new institutions, processes, and methods for restoring to the playing field of governance some of the normative questions that were sidelined in celebrating the benefits of technological progress? And are there structured means for deliberating and reflecting on technical matters, much as the expert analysis of risks has been cultivated for many decades?[1]

[1] Jasenoff S, 'Technologies Of Humility: Citizen Participation In Governing Science' (2003) *Minerva* ***41:****226–267.*

Whereas stage 3 was about setting the groundwork for public participation, this new stage 4 is about effecting and institutionalising public participation in legal frameworks. It reflects a paradigm shift from what 'should' be done, to what 'must be done'. That is, stage 4 involves moving from participation as a 'policy', towards established and integrated mechanisms that *guarantee participation* as practice.

As will also be discussed below, legitimising risk regulation requires more than just inducting stage 3 risk communication practices into regulation. Instead it obliges an extension and development of regulatory and administrative law principles to make the *law itself* more participatory, deliberative and inclusive. That is, not only must the regulatory framework ensure effective democratic involvement in risk analysis, but the process of establishing, enforcing and maintaining that regulatory framework must also *be democratic*. I will refer to this below as 'deliberative risk governance'.

The Need for Institutional Frameworks. Whilst the NHMRC Report did not set out a complete model for risk communication, it did emphasise that risk communication needed to be underpinned by *actual legal mechanisms*. The move towards institutionalisation of the participatory risk communication model was seen as necessary for two primary reasons.

The first was to countermand the power differential between key agents in the risk analysis process. It probably goes without saying that certain parties in a political or legal deliberation will generally dominate discussion because of their status or resources. The only real way to force open the debate and make it more egalitarian is to provide an institutional guarantee that all interested parties are not only heard but given equal weight.

The second justification is that institutionalisation brings process legitimacy. Risk analysis thus far has been about the standardisation of processes into an accepted framework. This framework is mutually accepted and adopted by scientists, regulators and among the international community. It ensures and equally importantly creates the appearance of, a systematic and scientific approach to risk

governance so that risks are dealt with – and have the appearance of being dealt with – in an effective and predictable way. The same can be said of regulation generally. Hall argues that:

> underlying the introduction of a new law … are value judgments about what activities are important in society and how they should be regulated.[2]

Regulation is very much a case of setting down societal principles 'in stone'. In doing so the legislature legitimises community concerns by making a clear unequivocal statement as to what is to be acceptable and what is not. It confirms that these concerns will be dealt with in an effective and predictable way. Hence, if risk communication is to be accepted as an crucial component of risk governance, it must be legitimised by providing it with visible institutional underpinnings.

12.1 THE INTERNATIONAL CONTEXT

The movement towards process legitimacy cannot be precisely defined. However, there are a growing number of international agreements, which point toward the development of a more formalised structure for risk communication. These international laws, guidelines and practices have a real and lasting influence on domestic risk practice and the implementation of risk regimes such as the *Gene Technology Act* 2000 (Cth) (GTA/the Act).

As of yet, the participatory model has had mixed support in the international risk analysis laws and rules. This is primarily because such laws set out obligations as between member states rather than between state and subject.[3] The only real

[2] Hall K, *Legislation*, Butterworths, Australia, 2002, p 12.

[3] For instance, the Convention on Biological Diversity requires notification, information exchange and consultation on risks to biodiversities of other States [Art. 14(1)(c)] and to notify another convention party of any LMOs entering its country [Art 19(4)]. Under the *Biosafety Protocol* parties are required to share information and notify other parties on risk assessment and risk management procedures [Arts 7-12]. The SPS agreement requires notification to other members states of any sanitary or Phytosanitary measures which could affect exports to that country [Art. 5(8)] or of any phytosanitary laws which would affect the use and import of goods into that country [Article 7].

international treaty relevant to gene technology, which refers to the participatory risk communication model is the Biosafety Protocol.[4] Nevertheless, the participatory model has proliferated in many of the standards set out by international agencies. As I outlined above [see 7.1.2] the most influential international standards on domestic legislatures are those set out under the rubric of the WTO agreement.

12.1.1 STANDARDS SET OUT UNDER WTO AGREEMENTS

The *Agreement on the Application of Sanitary and Phytosanitary Measures* 1995 (SPS) and the *Agreement on Technical Barriers to Trade* (TBT) [see 7.1.2] contain no direct mention of any risk communication measures *per se.* Both however, require 'transparency' between member states.[5] This transparency requirement basically obliges members to provide a full and frank disclosure of decisions, rules, measures and standards to other member states.[6] However the obligation provides an incidental power to states to pass on information to their citizens should they so choose.

The rules within the WTO agreements relating to risk governance are expanded by virtue of the incorporation of 'international standards' such as those set out by the Codex Alimentarius Commission (CODEX), the Office International Des Epizooties (OIE) and the Secretariat to the International Plant Protection Convention (IPPC), [see 7.1.2]. All of these 'international standards' deal with the domestic application of the risk analysis process. Within this context it is relevant to consider the risk communication practices agreed to under these standards.

Codex. Following the Orange Book report, the Food and Agriculture Organisation and World Health Organisation (FAO/WHO) broadened the role of risk communication under the CODEX agreement to include set goals. These were to:

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[4] This said, some regional agreements to which Australia is not a party, i.e. the *Convention on Access to Information, Public Participation in Decision-making and Access to justice in Environmental Matters* (Aarhus Convention) specifically require democratic risk communication as part of risk analysis.

[5] art.7, SPS . arts, 2.9.1-2.94, 2.10.1- 2.10.3, TBT.

[6] For example see generally Annex B , SPS.

- improve the effectiveness of the overall process;
- promote transparency in risk management decision making;
- promote awareness and understanding of specific issues of risk analysis;
- strengthen working relationships with participants;
- exchange information among interested parties; and
- foster public interest and risk analysis management.[7]

The definition of risk communication by Codex was also expanded, and now reads:

> Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.[8]

FAO/WHO. FAO and WHO have continued to broaden the scope of for risk communication within the overall risk analysis paradigm, especially in relation to gene technology.[9] This includes a particular emphasis on participatory forms of risk communication from 'all interested parties, including government, industry, academia, media and consumers'.[10] Transparency, openness and accountability is

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[7] Chevassus-au-Louis B, *Prevention, Precaution, Consumer Involvement: Which Model for Food Safety in the Future?*, Paper presented at the OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods 11 (Feb. 28-Mar. 1, 2000) p 12.

[8] Codex Alimentarius Commission, *Procedural Manual*, 12th Ed., Joint FAO/WHO Food Standards Programme 2001.

[9] *Draft Principles For The Risk Analysis Of Foods Derived From Modern Biotechnology*(At Step 8 of the Elaboration Procedure) also art.16 *Draft International Code of Conduct on Plant Biotechnology* (FAO).

.[10] See Codex Alimentarius Commission, *Report of the Joint Fao/Who Food Standard Programme, 24th Session Geneva, 2-7 July 2001* Report (ALINORM 01/34A E), World Health Organisation, Geneva 2001, Appendix II par 22.

now considered central to legitimising the process.[11] However, commercial confidentiality and the protection of industrial information are still considered imperative and cannot be derogated from.[12] The committees also recommend 'responsive consultation processes', in which discourse is interactive and all views and concerns are addressed.

Office International Des Epizooties. The participatory, integrative process has been adopted in the OIE Codes [see 7.1.2], which additionally recommend that any assumptions and uncertainty in the model as well as all risk data should be communicated to 'participants'.[13] They define risk communication as 'a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout'.[14] Those the OIE recommends participate in risk communication include: authorities in the exporting country; stakeholders;[15] conservation and wildlife groups, domestic and foreign industry groups and consumer groups. These bodies should have access to all relevant information including 'assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment'.[16]

International Plant Protection Convention. The IPPC has some rather vague references to the need for 'technically justified, transparent' phytosanitary measures, but does not extend the concept into any form of public risk communication.[17] Nor do the IPPC risk analysis guidelines[18] mention any need to consult with the public in the protection against the introduction of alien species. This is rather unfortunate given the Convention's relevance to agricultural gene technology. The lack of development of risk communication within the IPPC

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[11] *ibid.*

[12] *ibid.*

[13] see art. 1.3.2.7. International Animal Health Code; art. 1.4.2.7, International Aquatic Animal Health Code.

[14] art.1.3.2.7.1, International Animal Health Code, art. 1.4.2.7.1 International Aquatic Animal Health Code.

[15] Including domestic and foreign industry groups, domestic livestock producers, domestic aquaculturists, and recreational and commercial fishermen.

[16] *a*rt.1.3.2.7.5 , International Animal Health Code, art.1.4.2.7.5 International Aquatic Animal Health Code.

[17]art. 16, International Plant Protection Convention (Food and Agricultre Organisation)1952. Of course the agreement requires a high level of risk communication between member states[Art. 8].

[18] Secretariat of the International Plant Protection Convention, *Guidelines for Pest Risk Analysis* International Standards for Phytosanitary Measures no.2, Food & Agriculture Association, Rome, 2002.

when compared to the OIE is likely due to the differences in the level public scrutiny upon their respective subject matters. The media furore over 'mad cow' disease has necessitated a broad scale risk communication policy for animal risk analysis.[19] On the other hand plant diseases and risks have not received concomitant attention. Given that the Convention falls under the auspices of the FAO, and that the FAO has been a driving force in the effort to establish participatory risk communication within biotechnological risk analysis,[20] such a position is likely to change.

12.1.2 CONVENTION ON BIODIVERSITY

The *Convention on Biological Diversity* (CBD) 1992 has been ratified by Australia and is binding on domestic law. The CBD was drafted at the same summit (Rio Earth Summit) as Agenda 21 [see 11.5.2] and like that document, reflects more of a stage 3 model. That is, it tends to set out broad directives but never specifically spells out the mechanisms by which participatory risk communication might be achieved. However, unlike Agenda 21 it is a formalised treaty which creates duties upon ratifying states, (of which Australia is a member). Of equal importance, the Convention is a significant foundation document, which has furthered the development of more recent environmental and health safety frameworks, for instance the Biosafety Protocol [see below].

Despite being primarily a stage 3 document, elements of the Convention do indeed support a participatory model for risk communication. This is clear from the Preamble of the convention, in which contracting parties are:

> [a]ware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop *scientific, technical and institutional capacities* [emphasis added] to provide the basic understanding upon which to plan and implement appropriate measures,

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[19] A good example of the concern over these issues is evidenced on the OIE website : <http://www.oie.int> and OIE instructional video see <http://www.oie.int/real/oie_us_presentation.rm> (1/12/02).

[20] Executive Committtee of Codex, *Draft Principles For The Risk Analysis Of Foods Derived From Modern Biotechnology*, As approved at 47th Session of the Executive Committee of Codex, Codex Alimentarius Commission, Chiba 2001.

The Convention also requires the promotion and encouragement of understanding of, the 'measures required for, the conservation of biological diversity'.[21] It contains a limited provision for 'public participation' in environmental impact procedures. The need for participation is restricted, in that such measures are only required, 'as far as possible and as appropriate' and only where the environmental impact assessment is for activities likely to have 'significant adverse effects on biological diversity'.[22]

Biosafety Protocol. The more recent annex to the Convention on Biodiversity, the Biosafety Protocol [see 7.1.2] sets out more specific institutional mechanisms for the achievement of participatory risk governance. It *requires* parties 'promote and facilitate public awareness' in regard to risk practices and rules.[23] The Protocol also mandates public consultation during the decision-making process regarding living modified organisms.[24] It declares that 'transparency' is a fundamental principle of the risk assessment process.[25] Parties must further ensure that public access to information is permitted,[26] including any decisions made in respect of living modified organisms.

Of course the Biosafety Protocol is not ratified by Australia, nor is it likely to be.[27] Nevertheless, it provides important guidance and is likely to be observed in practice so as to minimize trade discrepancies between ratifying and non-ratifying parties.[28]

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[21] art.13(1)(a), *Convention on Biological Diversity* 1992, <http://www.biodiv.org/doc/legal/cbd-en.pdf>.

[22] *ibid.* 14(1)(a).

[23]art. 23(1)(a), *Biosafety Protocol.*

[24] art.23(2), *Biosafety Protocol.*

[25] annex III.3, *Biosafety Protocol*.

[26] art. 23(1)(a), *Biosafety Protocol*. It also requires that the Public must have access to and be informed of the biosafety clearing house, which contains information on living modified organisms, risk assessment and risk management information and any laws concerning their use, art 20, & Annex I, *Biosafety Protocol*.

[27] Ralph Hillman, 'Cartagena Protocol on Biosafety. Speech—Australia's Position', Senatorial Website web site :

<http://www.dfat.gov.au/environment/bsp/hillman0300.html> (3/2/03).

[28] "[W]e were conscious that if our key trading partners become Parties to the Protocol, Australian trade in LMOs would be affected by the Protocol regardless of whether we became a Party" *ibid.*

UNEP Technical Guidelines. The *UNEP International Technical Guidelines for Safety in Biotechnology 1995* (UNEP Guidelines) were adopted as a precursor to the Biosafety Protocol[29] and in the absence of Australia's ratification of that protocol remain directly relevant to risk practices here. The Guidelines are intended to contribute to the implementation of Agenda 21 [see above] and to assist in fostering the development and standardisation of risk practices in relation to gene technology.[30] The Guidelines state that:

> [a]s set out in Agenda 21 and relevant provisions of the Convention on Biological Diversity, authorities/national institutional mechanisms are responsible for encouraging public participation … This should allow for local knowledge and circumstances to be taken into account in risk assessments. Users are encouraged to enter into dialogue with their staff/personnel as well as with the general public and workers about their activities.[31]

Methods for encouraging public participation are suggested in Annex 7 of the Guidelines. They include:

- establishing a register of GMOs with a summary of risk data on those organisms;
- giving interested groups the opportunity to comment on proposals to work with organisms with novel traits;
- encouraging those releasing GMOs to notify local people;
- encouraging dialogue between companies and academic institutions working with organisms with novel traits and public interest groups; and
- utilising conventional and electronic media to disseminate information on GMOs and GMO risk information.

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[29] Decision 18/36 B of the Governing Council of UNEP 1995, para 8.

[30] *International Technical Guidelines for Safety in Biotechnology* (United Nations Environment Programme) 1995 :
<http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm> (3/5/02).

[31] *ibid,* para 34.

12.2 ADOPTING AN AUSTRALIAN MODEL RISK COMMUNICATION

The guidance provided by international documents, particularly those of the WTO, has a direct impact on how we regulate domestically.[32] How Australia has effected this guidance with respect to gene technology will be dealt with comprehensively in chapters 15-18 in the examination of the risk communication mechanisms within the GTA. Nevertheless, it is worth examining the current status of risk communication in Australia as a whole, and how the international move towards institutionalising participatory risk communication has been affected here. This will provide a basis upon which to reflect whether the risk communication provisions of the GTA meet with current 'best practice' policy set out by Australian Guidelines.

As has been noted previously, [see 7.1.3] the current Australian benchmark for risk analysis is set out under the Australian Commonwealth National Health Partnership (NHP) *Guidelines for assessing human health risks from environmental hazards'* (the Guidelines). The Guidelines are intended to provide a national best-practice approach to health and environmental risk analysis.[33] It must be reiterated that the guidelines were created subsequent to the GTA. However, they are relevant as they:

- provide an insight into what stage of risk communication Australia is currently in;
- affect the way the risk procedures within the GTA are undertaken; and
- provide a comparative basis to examine what mechanisms exist, or indeed are absent from the GTA.

The Guidelines highlight that:

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[32] Council of Australian Governments, *Principles And Guidelines For National Standard Setting And Regulatory Action By Ministerial Councils And Standard-Setting Bodies*, Commonwealth of Australia (AGPS), Canberra, 1997, pg 8.

> [t]here is a growing awareness of the need for appropriate community consultation and involvement. The process may not lead to consensus, but it is likely to ultimately smooth the passage of a proposal to increase the validity of the risk management process, and to provide information that is useful throughout the risk assessment and management steps.[34]

The Guidelines recommend that the overall process of risk analysis should be undertaken as a 'partnership' with the community 'commensurate with the potential effects on the community'.[35] They describe community involvement as an essential part of the overall process because risks 'cannot be managed without addressing human behaviour'.[36]

The guidelines recommend that public and stakeholder involvement should be an inherent part of risk assessment *and* management as these parties:

- have general 'right to know',
- have local knowledge as sources of exposure and patterns of behaviour,
- understand 'local concerns',
- may expose issues not identified by conventional risk assessment

Risk communication is defined by the Guidelines as 'an interactive process involving the exchange among individuals groups and institutions of information and expert opinions about the nature, severity and acceptability of risks and the decisions taken to combat them'.[37] It is intended that the process enable all stakeholders and members of the public to make an 'informed judgment about a risk and its management'. [38] This must be, and be seen to be a 'a genuine process conducted with the community's interest in mind'. Risks and uncertainties should be described in a 'frank and open' presentation of all relevant facts.

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[33]National Health Partnership, *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia (AGPS), Canberra, 2002.

[34] *ibid.* p 17.

[35] *ibid.*

[36] *ibid.* p 18.

[37]*ibid*, p 16.

The Guidelines state that, good risk communication will assist decision makers to better 'understand public perceptions', 'anticipate responses' and 'respond to public concern'. Participatory risk communication will assist in explaining risks 'more effectively and in correcting misperceptions all stakeholders (including the public, the decision-maker and risk assessors) of actual risks. In doing so it will 'reduce unwarranted tension' and 'address disquiet' about the processes adopted for risk attenuation.

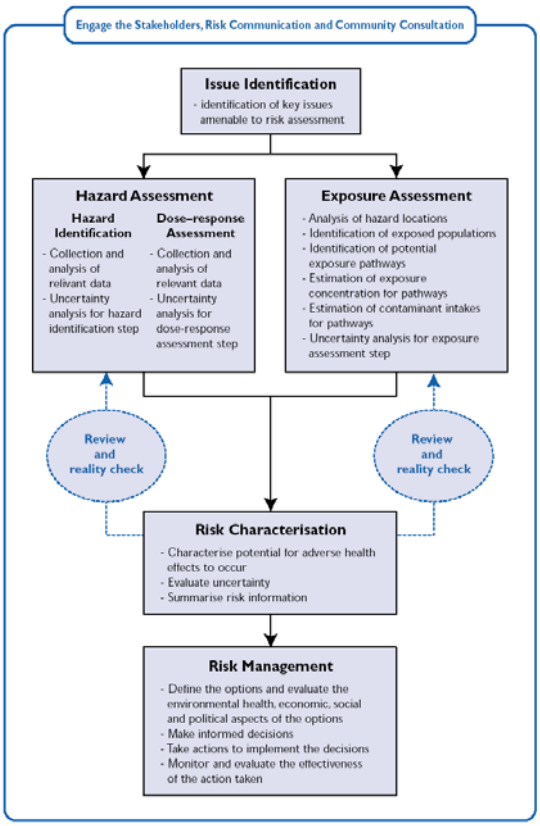

FIGURE 5

The Process. The Guidelines state that legitimacy will be gained by 'focusing on issues and processes rather than people and behaviours.'[39] This is necessary because, '[t]rust, credibility, competence, fairness and empathy are often as important to the community as statistics and scientific details'. Hence the Guidelines recognize the need for process legitimacy.

Figure 5 (pg 345) shows the process of risk analysis as envisioned by the NHP. The process clearly requires risk communication to be undertaken at every stage of the risk analysis process. The Guidelines identify, in detail, how and why community involvement could be integrated into each step of the risk analysis process. This includes;[40]

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[38] *ibid.*

[39] *ibid.* p 20.

[40]The objectives for each stage of the risk assessment process should be examined to determine the nature of the community consultation." *ibid.* pp 18-20.

- anticipating issues;[41]
- using communication plans;[42]
- consult at every stage of the process;[43]
- reinterpreting risk data for each party to the deliberation;
- exchanging information about the risk analysis process; [44]
- adopting the right attitude;[45] and
- evaluation of the consultation.[46] .

12.3 REFORMING EXISTING STRUCTURES

What can be seen at both the international level and domestic level is a genuine move towards creating real process and procedures to *ensure* that the public is *actually* involved in risk governance. There is a general trend towards extending existing legal structures which govern technological risks, to make them more participatory and more orientated towards the public interest. The following discussion outlines the dominant features of this reform, and how it affects the way in which Australia regulates risk.

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[41] Including lack of communication skills, or confusion about the process, by any party, limited time, resources and staffing, cultural issues, conflicting interests among parties, the media, policies, agendas and political pressures.

[42] A risk communication plan should include: Whether materials will be needed, ensuring that they are pre-tested and evaluated afterwards; What groups should participate, how they may participate and how they may be brought into the discussion. 'Anybody who perceives themselves to be affected should be able to participate in the process'; How industry will be involved; How to effectively communicate with the media; How concerns and responses will be sought and integrated into the final decision; What form of meetings will be necessary, small, informal meetings are more effective. If larger meetings are necessary that there are measures to foster better participation; Choosing the right Chair for a meeting. The chair should not appear partisan or biased and should impart credibility to the process.

[43] *ibid.* p 19.

[44] including why and how the risk assessment and management is being undertaken and how various stakeholders may be involved.

[45]Recognising that the manner of delivery is as important as the message; it must be 'honest, realistic and open; appreciating that intentional communication is often only a minor part of the message actually conveyed'. *ibid,* p 20.

[46] This should occur throughout the overall process, to make adjustments and improvements. Evaluation should include whether the communication was timely and sufficient; and the effect upon and response by, both the community and the organisation.

The Limitations Of Conventional Administrative Law To Risk Governance. The current set of international and domestic benchmarks for risk communication advocate building upon normative legal structures such as transparency and freedom of information and making them more inclusive, pre-emptive and responsive. We can see in such benchmarks an enduring process, first envisioned by Reich, that advocates expanding the law to ensure a true respect for and an account of the public interest.

Why has this process necessitated expanding the conventional administrative law mechanisms? I would contend that existing mechanisms are insufficient to regulate technological risk, particularly where the subject matter is novel, technical and commercially driven. Such mechanisms cannot, and do not, ensure a respect for, and an account of, the public interest. This is because:

- novel technologies differ from contemporary subjects of regulation, in that they present unforseen risks and concerns which require constant re-identification and deliberation;
- administrative law principles are generally unidirectional and retrospective, as they are designed around ensuring review of a decision which has already been made. Such review, whilst necessary, is insufficient in respect of risk governance of novel technologies;
- risk information requires more than simple transparency or freedom of information. Technical data, on which such decisions are made, must be reinterpreted and explained to lay persons. This process of reinterpretation is one which itself may be susceptible to bias;[47] and
- much of the risk assessment process occurs outside of direct regulatory intervention. Scientists or risk assessors external to the regulatory agency itself undertake much of the process of information gathering, processing and review. This process is extremely influential on the eventual decision made. Hence there is a need to extend the sanction of the law to cover this aspect of the decision making process.

[47] Otway H, Wynne B , 'Risk Communication: Paradigm and Paradox', (1989) *Risk Analysis* **9**:141.

A Perpetual Process. To truly institutionalise participatory mechanisms in risk governance requires both an extension of traditional public participation legal theory and a restructuring of regulatory practice. In the constant flux of technological development, it is not simply enough for the public to identify matters of concern then empower a regulator to guard against such matters. Rather, a regulator of novel technology will have a constantly shifting mandate and the public a continuing interest in identifying the breadth of that mandate. The NHP Guidelines [see 7.1.3, 12.2] emphasise that risk communication 'should not be seen as a retrospective form of community involvement and consultation'. *Ex post facto* oversight provides only a partial solution, which must be reinforced with active participation in the actual assessment and management process itself.

12.4 MAKING, DOING AND ENFORCING

As risk communication moves toward process legitimacy, there is a realisation that the entire risk governance process must be subject to a degree of deliberation. Thus, the Convention on Biological Diversity's preamble calls for the increased awareness of and sharing of information about institutional capacities to plan and implement appropriate measures for the preservation of biological diversity. In other words, the *mechanisms* for risk governance must be subject to interactive communication and deliberation, just as the subject of risk governance is. This premise is taken up by the National Health Partnership Guidelines, which reinforce that to truly gain public acceptance, requires focusing on both 'issues *and processes* [emphasis added]'.[48] This is because proper risk governance 'entails knowing how to respond to public concern and is a genuine process conducted with the community's interest in mind.'[49] In other words, the community should not only play a role in risk analysis (*doing, enforcing)* but also in determining the scope and nature of the laws which underpin that actual processes, that is the making or reforming of law. The acceptance of the need to involve the public in the development of need to involve the public in determining

[48] National Health Partnership, *Guidelines For Assessing Human Health Risks From Environmental Hazards*, Department of Health and Aging and Health Council, Commonwealth of Australia,2002. p 20.

[49] *ibid*, p 20.

the legal mechanisms, which would underpin the proposed regime, was recognised early in the Commonwealth's Biotechnology Strategy, in which the Government stated:

> [i]n order that there is public confidence in biotechnology, it is essential that the community continue to contribute to the development of Government policy… [and the Government would] engage the community in discussion of regulatory processes … and assessing and managing risks to human health and the environment …[and] encourage public contribution to policy decisions.[50]

The move towards involving the public in all aspects of the regulatory process, including in determining the form and scope of that process has been mirrored in domestic practice. The 1995 Attorney General's Justice Statement outlines Commonwealth policy relating to law making as follows.

> The Government is committed to public consultation in the development of laws. Such consultation contributes to a greater understanding of new laws, and makes those laws more responsive to community needs. Public consultation can also assist in improving the clarity and content of proposed legislation. [51]

Since 1998 it has been a mandatory policy requirement for any Commonwealth body making, enforcing and reforming Commonwealth Law to consult with those affected by proposed changes from an early stage of its development and provide evidence that such feedback was taken into account. [52] Such an obligation was

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[50]Commonwealth Biotechnology Ministerial Council, *National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 1999, p 11.

[51] Commonwealth Attorney General's Department, *The Justice Statement* ,AGPS Canberra 1995 ; Guideance on consultation in legislative reform is also be found in Administrative Review Council, 1992, Report to the Attorney-General *Rule Making by Commonwealth Agencies, Report No 35*, AGPS, Canberra.

[52] Departments must complete a Regulatory Impact Statement in compliance with the Office of Regulation Review Guidelienes - Office of Regulation Review, *A Guide to Regulation*, 2nd Ed, Commonwealth of Australia, Canberra, 1998 section A1.

Such bodies must, as part of a Regulatory Imact statement ensure that those affected by proposed legislation are consulted at an early stage of its development. Responses received from these parties needs to be taken

extended to the creation or reform of statutory instruments in 2003. Whilst that obligation is limited to situations where the statutory instrument would impact on business or trade it does indicate a greater willingness to provide involve affected parties in every aspect of the regulatory process. It also indicates the development of traditional administrative law into more inclusive, pre-emptive and responsive forms.

To truly gain process legitimacy, the whole structure and the very architecture of risk regulation needs to be subject to the democratic processes learnt in the development of risk communication theory. Stage 4 communication encompasses, not only the process of *doing* law, (i.e. risk assessment and management) but also *making* and *enforcing* it. For the sake of clarity this will be referred to as *deliberative risk governance* ['risk governance' is defined at 7.1.5].

I shall expand on the conflation of regulatory theory and risk theory below. However to clarify what is meant by the process of deliberative risk governance within the context of this thesis, I would define it as, analytic, deliberative communication:

- *during pre-drafting,* to set the groundwork for what concerns exist, what should be regulated and how it should be regulated;
- *during the drafting process*, to ensure the mechanisms adequately deal with public and stakeholder concerns and are technically, legally and socially acceptable;
- *within the regulatory process*, this is the traditional notion of risk communication [see above];

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into account in determining the most appropriate regulatory option. [sect A8]. Relevant bodies that must be consulted with inlclude: "other departments and the general community"[sect D5] ; "business, consumers, unions, environmental groups and other interest groups which will be affected by the regulatory process" [sect b4]. Consultation is viewed as a whole and the agency is permitted to take into account consultations undertaken as part of the overall legislative process, particularly submissions given to parliamentary committees. See Department of Prime Minister and Cabinet, *Legislation Handbook*, AGPS, Canberra 1999 para 1.8.

Consultation is also obligatory under part 3 of the Legislative Instruments Act 2003 where changes to subordinate or delegated instruments might have a substantial effect on business or restrict competition.

- *about the regulatory process*, to review and scrutinise the effectiveness of regulation to existing and new risks, and
- *about regulatory behaviour*, to establish whether the form of the law is being adequately applied, whether the processes for risk governance are working in practice and whether the regulator is truly acting in the public interest.

In other words deliberative risk governance refers to a holistic approach to public involvement, infusing public feedback into every aspect of the law. There are various reasons for this apparent correlative development and confluence of risk and regulatory theory. These are extrapolated upon below.

Creating Trust. Public participation in the making and enforcing of risk regulation can be seen as integral to creating trust in the regulation and residually in the risk analysis process itself (once implemented). From its inception to its implementation, regulation will be held up to public and sectional scrutiny. Thus, from the outset, deliberative risk governance will be imperative to creating trust in a proposed system. Public input into the effective operation of the system, including the opportunity to 'fine-tune' or contribute to regulatory reform will foster trust that the system will adequately cope with new and novel risks as well as properly controlling existing ones.

Democracy. From an ideological perspective, deliberative risk governance is reflective of the democratic notions which underpin the current risk communication paradigm. Public consultation on proposed regulatory initiatives and the review of existing law ensures that sectional interests can be represented, promoted and perhaps incorporated within the final framework. Thus, Miers and Page conclude that consultation is an 'important and necessary [channel] of communication which parallel [sic] representation through the electoral system'.[53]

Ostracising the community from risk governance, may actually result in more profound political repercussions if it occurs before a regime comes into effect. As Mackintosh points out, disillusionment with proposed legislation will result in

[53] Miers D, Page A. *Legislation* 2nd Ed, Street & Maxwell, London 1990, p 41.

concerted lobbying by groups with the capability to 'limit, deflect and even frustrate government initiatives'.[54] Failure to consult may 'make the passage of legislation more difficult' or indeed halt it altogether.[55] Even if such legislation is realised, early animosities created by a lack of participation are likely to linger on. As Slovic and MacGregor state,

> The limited effectiveness of risk-communication efforts can be attributed to the lack of trust. If you trust the risk manager, communication is relatively easy. If trust is lacking, no form or process of communication will be satisfactory … Thus trust is more fundamental to conflict resolution than is risk communication.[56]

Simply put, 'first impressions count' and if the community does not feel included in legislative design, it will be harder to gain their trust once the system is in place. This is particularly so when, as with gene technology, there is already a perceived lack of transparency. In such a case the legislature is on the 'back foot' needing to evince a particularly strong intention to listen and respond to public concerns.

Better Identification Of, And Response To, Risks And Concerns. From a practical perspective, non-governmental bodies, particularly sectional groups, provide a high level of degree of expertise and knowledge in the subject matter of regulation or proposed regulation. Much as risk communication allows those affected to identify key issues and risks, deliberative risk governance allows for such risks and issues to be met with *actual regulatory mechanisms*. Davies highlights the importance of non-governmental bodies in the drafting process:

> [l]egislatures themselves are seldom in the position to invent an idea, draft that idea into a bill, educate the press and public to the bill's merits, or lead a lobbying effort in both houses of the legislature and the executive branch. It is unrealistic to expect them to do so. What actually happens is that new ideas in the

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[54] Mackintosh J. P, *British Cabinet*, 3rd Ed, Stevens & Sons Ltd, London, 1977.

[55] Miers D, Page A. *Legislation* 2nd Ed, Street & Maxwell, London, 1990, p 41.

[56] Slovic P, MacGregor D. M, *The Social Context Of Risk Communication*, Decision Research Report No. 02-06, Eugene, OR: 1994, p 17.

> form of draft bills are brought to legislators by citizens, scholars, lawyers, bureaucrats, and lobbyists.[57]

Gene technology is highly complex, not only because of its scientific or technical nature, but because of the complex social and ethical repercussions it creates. Public consultation is especially necessary, so as to provide legislators with a complete understanding of the breadth of these concerns. Falkiner argues that scientific legislation often fails, because drafters neglect, from the outset, to obtain a clear understanding of the technical nature of the subject matter and its social repercussions.[58]

Early failures to understand what is required necessitate constant 'quick fixes', until the legislation becomes unwieldy, unstructured and unworkable. Poorly structured legislation, Falkiner argues, 'becomes very difficult to amend without the amendment triggering off unintended side effects'.[59] It is then imperative that legislative draftsmen are as aware as they can be about the technology, its science, its technicalities, its repercussions and its risks. The means by which this information will be elicited, will be consultation with community, industry and academics. Without adequate consultation, legislation would be created in a vacuum without regard to its impact, efficiency, applicability or consequences.[60]

Informing the Public. Finally, deliberative risk governance is important so as to inform the public as to the nature and indeed existence of the Act itself. A failure to adequately describe the subject or the nature of the proposed legislation will lead to confusion over the scope of the law or the mistaken perception it does not adequately deal with certain risks. Such a law would not be trusted to adequately protect against perceived risks.

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[57] Davies J, *Legislative Law and Process* 2nd ed, West Publishing, Minnesota, 1986, p 3.

[58] Falkiner T, *Scientific Legislation*, Aristoc Press, Glen Waverley, 1992, p156.

[59] *ibid*, p156.

[60] Or to state it bluntly, legislation would be the creature of 'tyranny of ignorance', by a 'rigid and stupid bureaucracy Finer S.E, *Anonymous Empire: A Study of the Lobby in Great Britain*, 2nd Ed, Pall Mall, London, 1966, p 113.

12.5 THE PITFALLS

What are the pitfalls of such a model? The primary problem must be the potential for recalcitrance on the part of those charged with implementing and overseeing it. The relative modernity of the model makes it hard to determine when or if it will permeate into regulatory procedure. There has been a long case history of risk communication being good policy but bad practice. [61] As will be discussed below, this remains an unfortunate truth of gene technology risk communication – something that may have been evident above and will be discussed below [see 13.1-13.3]. The only way to ensure that this is not the case is to implement actual and effective regulatory mechanisms that compel the use of participatory risk communication models. Yet, there is a danger in sealing policy in legislation. If history serves true, risk communication policy is likely to undergo further expansion and development, which would leave such mechanisms out of step with current practices. This presents a real challenge for legislative drafters and regulators.

Over Reliance on Public Data. Another potential problem with the participatory model is the potential for decision makers to rely *too* heavily upon it as a decision-making device. Risk communication cannot become 'an end in itself' so that it replaces rigorous risk analysis practices.[62] It must integrate and compliment risk assessment and management, rather than replace or dominate them. Risk communication, could prove an attractive avenue to offset pressure on a regulatory agency. Broadening the decision making process should not derogate from the responsibilities of a decision maker.

The great weight given to risk assessment practice is likely to diminish the impact risk communication will have on the quality of risk practices. However the tendency to offset the costs of regulation, coupled with the lack of complete technical expertise within the regulatory agency creates at least a potential for over-reliance or over emphasis on data from bodies external to the agency.

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[61] McGarity T, 'Seeds Of Distrust: Federal Regulation Of Genetically Modified Foods' (2002) *University of Michigan Journal of Law Reform* **35**:495.

[62] Power M, *The Audit Society: Rituals of Verification*, Oxford University Press, Oxford, 1997.

The Costs. One of the most prominent concerns about risk communication and one which has played a large part in the reluctance of risk managers to implement it, has been the costs associated with it. The issue of costs will undoubtedly be compounded as the process expands into all aspects of risk governance. Requiring public consultation and sectional input at every stage of the process will undoubtedly impede the approval of commercial crops. This is both contrary to the Government's policy of facilitating commercialisation [see 14.3.2] and ensuring that regulation has minimal impact on business.[63] Time and money will also have to be expended to establish and maintain a suitable infrastructure for the provision of multi-directional communication and experts capable of reinterpreting technical and legal information for different groups.[64]

Commercial Repercussions. Related to economic concerns is the potential for unfettered access to risk information to have commercial repercussions. This is particularly so where the products of those inventions are in development or in a trial phase and may not have received intellectual property protection. In an 'information economy' many aspects of the data about the product, the company or indeed the risks it poses will have real and pecuniary value, which could be diminished by disclosure. All of the abovementioned regimes include provisions for the protection of such information, the importance of which will be discussed below [see 18.1.3].

Imbalances in Representation. Perhaps the greatest pitfall in opening the decision making process to greater public involvement is that the 'public' will not involve themselves nearly to the degree hoped, but rather pressure or interest groups will dominate the dialogue. Such groups are a common feature of the political landscape. They have varying influence on the regulatory process, but their impact

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[63] "Regulation should be designed to have minimal impact on competition. Although it may be necessary, for example, to regulate some aspects of commercial practice, regulation should avoid imposing barriers to entry, exit or innovation." Council of Australian Governments, *Principles And Guidelines For National Standard Setting And Regulatory Action By Ministerial Councils And Standard-Setting Bodies*, Commonwealth of Australia (AGPS), Canberra, 1997, pg 8.

[64] Horlick-Jones T, 'Is Safety a By-Product of Quality Management?' in Hood C, Jones D, Ed., *Accident and Design*, UCL Press, London, 1996, p.151.

cannot be ignored. This influence is both important, in that it gives a unified voice to concerns in the community, and dangerous, in that some groups may have the ability to undermine regulatory initiatives, spread misinformation or actually alter public policy.[65]

A regulatory agency overseeing multi-directional communication must attempt to involve as many parties as possible and allow for each to be given equal standing and weight. Moreover, the lack of technical or legal expertise of some parties may result in their input being subsumed by those with the expertise or experience in the industry. Part of the process must be to attempt to raise those parties at a technical or legal disadvantage to a level where they may undertake meaningful dialogue with all parties to the deliberation. To allow one or more groups to dominate the dialogue will be counterintuitive to the whole purpose of risk communication. It would make the process appear biased, agenda driven and inherently 'undemocratic'.

12.6 CONCLUSION

The slow evolution towards standardised risk communication practices has been necessitated by continuing failures of those participating in risk governance to elicit public support for their activities. Whilst there have been some failures of risk assessors and managers, the lack of trust in risk decisions is generally the result of the exclusion (or at least perceived exclusion) of the public from the decision making process.

In a democracy, regulations are forged out of the melting pot of public concerns. The community – stakeholder groups in particular – is largely responsible for their promotion and implementation.[66] Even where Parliamentarians undertake the

[65] Miers D, Page A, *Legislation*, London, Street & Maxwell, 1990, p 23.

[66] "Legislatures themselves are seldom in the position to invent an idea, draft that idea into a bill, educate the press and public to the bill's merits, or lead a lobbying effort in both houses of the legislature and the executive branch. It is unrealistic to expect them to do so. What actually happens is that new ideas in the form of draft bills are brought to legislators by citizens, scholars, lawyers, bureaucrats, and lobbyists." Davies J, *Legislative Law and Process* 2nd ed, West Publishing, Minnesota, 1986 p 3.

promotion of regulation it is on behalf of their respective constituencies. To suddenly extricate the public from the process, simply because a regulatory regime has been implemented, is to fundamentally misapprehend the nature, context and source of regulation. As Otway states, risk communication is a 'political imperative in industrial democracies, since the participatory system is premised on the exercise of choice by an informed citizenry in elections and other public decision processes'.[67]

Just how to adequately include the public in risk governance is likely to be a continuing challenge. Certainly, the formalisation of processes and strategies for the achievement of participatory and democratic risk governance is ongoing. However, in terms of the realisation of community involvement in the overall process of regulating risk; understanding what is being strived for, will provide a major impetus for further development of institutionalised models for public participation.

What are the objectives of this process? Greater community involvement, it is hoped, will mitigate public misunderstanding of risk and the risk analysis process. Indeed, in a crisis situation, risk communication has been shown to placate public anxiety and mitigate the potential for public backlash.[68] This in turn, it is argued, will diminish the number of challenges to both the process and the decisions reached using the process.[69] Most importantly, deliberative risk governance is designed to foster trust by making the entire process accessible, transparent and interactive.

However, it is clear that deliberative risk governance is no panacea with which to legitimise all regulatory behaviour. Rather, it is a tool which must be properly managed so that its benefits and shortcomings are adequately balanced. Balance is required in a legislative capacity, so that statutory mechanisms mandate a minimal degree of public participation but concurrently ensure that there is sufficient

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[67] Otway H, 'Experts, Risk Communication and Democracy' (1987) *Risk Analysis* 7:**125**: 99.

[68] Santos, S. L, Covello, *v* T, McCallum, D.B, 'Industry Response To SARA Tide III: Pollution Prevention, Risk Reduction, And Risk Communication' (1996) *Risk Analysis* **16:**57-66.

[69] *ibid.* also Kunreuther H, Slovic P 'The Process Of Risk Management: Science, Values, and Risk' (1996) *The Annals of The American Academy of Political and Social Science* **545**:125.

flexibility to allow for further developments in policy and approach. Balance is important, so as to ensure that the social benefits of disclosure do not unjustly impact on the social benefits of a strong and competitive economy. Finally balance will be needed in a regulatory sense so that those overseeing the process ensure that all parties are represented and treated equally.

I would submit, in the vast proportion of cases, an informed public will arrive at the same conclusions that risk experts do, and certainly the NHP Guidelines [see above 12.2] support this view. The participatory process will 'smooth the passage' and legitimise decisions which would very likely have occurred through conventional risk analysis in any case. Nevertheless, those in charge of overseeing the deliberation process must be prepared to accept the potential that those involved will come to a different conclusion, fail to be swayed by risk data, or place weight in concerns which are perceived as 'irrational' by conventional risk assessors. Unless decision makers recognize the right of those involved to hold and express such opinions, *from the outset*, the entire process will appear a façade. Moreover, if the final decision has no relationship with the outcome of the public deliberation and was really *fait acompli*, the whole process will be undermined and trust lost. Decision makers must be prepared for a 'worst case' scenario, that the public may reject the technology altogether. If deliberative risk governance merely appears agenda driven it will not be seen to be truly participatory and will invariably fail.

13

GENE TECHNOLOGY AND RISK COMMUNICATION IN AUSTRALIA

In chapter 3 I provided a general history of gene technology and the changing public perceptions of it resulting from commercialisation. Recognising the descriptive nature of that chapter I wish to now discuss the social movement that was deemed a 'backlash' against gene technology within the theoretical construct of risk theory that has been developed over preceding chapters. Given the backlash was one of the main catalysts for legislative reform in the form of the *Gene Technology Act* 2000 (Cth) (GTA/the Act), it provides the key to understanding the underlying socio-political reasons the Act was deemed necessary by the Australian community. Hence this chapter is dedicated to resolving the primary question I asked at the outset of this thesis; 'why was the Gene Technology Act necessary?'

This chapter will examine the commercialisation of gene technology and what led to its regulation within the context of risk and regulatory theory – with particular reference to risk communication – developed over the previous chapters. This experience reaffirms that, without a regulatory imperative to do so, those in control of a novel technology (the so-called technocrats[1]) are unlikely to implement best practice risk communication. In the case of gene technology,

[1] Note that, because of the lack of any substantial regulatory regime at the time of commercialisation I use the term technocrats to describe any proponents who had control of technology – including beurocrats, industry and multinational corporations.

commercialisation resulted in what can only be described as sort of reflective 'micro-evolution' of the overall risk communication paradigm. Thus, we shall see that the initial approach to communicating about gene technology and its risks was very much a unidirectional stage 1 model. What gene technology proved is that such a process agitates the public and diminishes trust in technocrats and technology.

What I would further highlight from the experience is that pre-deliberative (stage 1-2) approaches cause the opposite also to occur. These strategies lead to an incomplete risk identification and therefore obfuscate risk managers as to the true risk perception in the community. As a result technocrats become disillusioned with the public's ability to 'understand risk' which leads them to distrust the public's ability to 'make the right decisions'. Thus, the traditional divisions between technocrats and the public become both entrenched and overt in the new technological enterprise. The reflexive stage 3 environment that arises as a result of such hostilities provides a platform for community deliberation, whether or not this occurs with the consent of technocrats. I would suggest that in most circumstances the community would use that platform to call for the implementation of institutionally legitimate mechanisms to impel transparent and deliberative risk governance. This is certainly the case with gene technology and the creation of the GTA.

13.1 REVISITING THE HISTORY OF GENE TECHNOLOGY

In chapter 3 I examined the use of and reaction to gene technology over a five year period. I chose the dates 1995 to 2000 because they mark;

- the approximate date of the introduction of genetically engineered foodstuffs into the international marketplace[2] and;

[2]The actual approval of the FLAVR SAVR Tomato by the FDA was in late 1994 [see Meyer R, , 'Detection Of Genetically Engineered Plants By Polymerase Chain Reaction (PCR) Using The FLAVR SAVR Tomato As An Example' (1995) *Z Lebensm Unters Forsch* 6: **201**:583. Martineau B, 'Food Fight', (2001) *The Sciences* 2:**41:** 24-29]. However, 1995 was chosen as the pivotal year because of the time taken for the issue to come to the attention of the larger public (especially in Australia) and academic commentators, [see Scalise D, Nugent D, 'International Intellectual Property Protections for Living Matter', (1995) *Case Western*

- the introduction of the Gene Technology Bill.

Whilst the gap between these two points may seem relatively short, there was dramatic increase in public awareness of and reaction to gene technology over this period. When in 1995 the first Australian study was undertaken into public attitudes [see 3.2] it was evident that many participants had never really considered genetic engineering in any tangible way. Gene technology was for them a prospective science, having little impact on their everyday lives. Their 'risk perception' reflected this, insofar as they expressed apparently conflicting perceptions of benefits and risks. Because the application of technology seemed a long way off, the risks were not perceived as actual, immediate or present. Therefore, the perceived future benefits of gene technology seemed to warrant its continued research and development.

There was also little socio-political interest in the technology. Governmental inquiries suggested there would be public concern about the technology but this did not translate into any immediate social drive towards regulation. One NGO had an incidental interest (through a single dedicated lobbyist) but this was not sufficient to create any real impetus towards reform.

Whilst it is easy to say that the 1995 public was generally unaware of gene technology, establishing the attitude four years on is much harder. By then it was a major political issue, the subject of media scrutiny and public debate. With so many interests in the community and so many opinions about the risks and benefits of the technology it is of course impossible to say definitively what public reaction was. However, I wish to use three primary indicators about the prevailing public attitude towards gene technology. These are:

- The Biotechnology Australia funded *Yann Campbell Hoare & Wheeler* (YCHW) study (1999). A random sample of the '**general public**' [see 3.10];

Reserve Journal of International Law, **27**: 83]. It was also during this year that the first major public surveys were undertaken to gauge public response to the introduction of the Tomato; [see Kelley J, *Public Perceptions of Genetic Engineering: Australia*, Final Report to the Department of Industry, Science and

- The *First Australian Consensus Conference On Gene Technology In The Food Chain*,[3] *Lay Panel* (the Lay Panel), was of course drawn from the 'general public' but can probably better be referred to as an '**informed public**' since they were provide with relevant information, allowed to listen to both sides of the debate and to deliberate on their findings [see 3.6];
- Stakeholder groups with active agendas relating to gene technology representing the broader '**active public**' [see 3.5].

The feedback from these groups was outlined in chapter 3. However, for clarity's sake I will summarise the main points and highlight some of the reactions that were common to each of these groups to draw a general picture of the public attitude at the time.

13.1.1 THE SAMPLE PUBLICS

The Consensus Conference and the Yann Campbell Hoare & Wheeler study both include randomly selected public samples and can be easily contrasted with the 1995 study. Hence I will deal with them together.

In both cases the sample publics (*general* and *informed*) were already aware of gene technology and most held some form of opinion about it – unlike 1995 survey group who needed 'reminding'. This is evidence of the large amount of information concerning gene technology in the public domain by this stage. Hence we can say that by 1999, the public were coming to view the technology as 'actual, immediate and present'.

Despite some recognition of gene technology's benefits there was a marked increase in the risk perception [see 3.2.4, 3.4-3.5, 3.8, 3.12-3.17] and a decrease in the acceptability threshold of both the *general* and *informed* publics. A number of

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Technology, May, 1995. (Revised August, 1997). Department of Industry, Science and Technology, Commonwealth of Australia, Canberra, 1997.

[3] *First Australian Consensus Conference Gene Technology In The Food Chain*, Lay Panel Report, The Australian Museum, Canberra, 1999, <http://www.austmus.gov.au/pdf/layreport.pdf> (10/10/02)

reasons were given as to why these groups perceived gene technology to be of high risk, many of which related to perceived ethical and social harms that it posed. Both groups felt that science should not be the primary determinant of whether the technology was acceptable – an issue not raised in 1995. Thus, we see the public reacting to a narrow technocratic view of risk and decision-making.

What was also evident was a diminution of trust in technocrats and decision makers over the previous four years. Despite interacting with and taking evidence from experts from across the political and scientific spectrum, the *informed* public was probably less trusting than the *general* public. However, both groups can generally be said to distrust the ability of those in control of gene technology to implement it in a manner according to the public interest.

13.1.2 THE STAKEHOLDER DIMENSION

Surveys are can hardly purport to be entirely representative of the whole population; a citizens jury is even less so. As Dietrich and Schibeci argue, random surveys tend to overlook how public sentiment and political governance is influenced in modern society.[4] Individuals tend to form into, or place their support in, hierarchal groups who can give greater influence to their interests. These sectional or stakeholder groups concurrently increase community awareness about these issues.[5] The more numerous the stakeholders, the more diverse their constituency and the greater their members, the more prevalent and more political that issue can be regarded. Consequently, these groups provide a richer social-political picture of the plurality of community views towards an issue than do smaller cohort studies.

The period of 1995 to 2000 saw a dramatic rise in the number of stakeholder and interest groups active in the area of gene technology. The relative lack of interest or awareness among the general populace in 1995 is evident from the existence of

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[4] Dietrich, H.& Schibeci, R. 'Beyond public perceptions of gene technology: community participation public policy in Australia.' Paper Presented at, *Towards Humane Technologies Conference* (15-17 July, 2002) , University of Queensland, 2002, pp 6-8

only the single active stakeholder GeneEthics – a small office with a one permanent lobbyist, within an environmental non-governmental organisation. By 2000, the situation was vastly different. Various existing stakeholder groups had taken up the issue of gene technology as they saw their interests being affected by it. Many others were created to address a gene technology specific mandate. These groups represented a wide range of communities and interests within Australian society, from ethical, environmental, consumer and health groups to producers, industry and science.

The vast majority of the *active* public were more concerned about than supportive of gene technology. Many called for the cessation of development and application of the technology until its risks could be adequately ascertained. Most were vocal about the need for regulation and actively participated in the consultation process for the Gene Technology Bill. This is not to say that all these groups wanted to stop the development of genetic technology altogether – although certainly some of the more extreme groups did argue such a case. Like the *informed* and *general* publics the *active* public generally expressed a high risk perception and a 'not in my backyard' mentality.

13.2 A BACKGROUND TO THE BACKLASH

For the most part, the public risk perception and 'benefit perception' of gene technology remained high between 1995 and 2000. The *general* and *informed* publics in particular show that at all times Australians recognised the potential advantages that the technology offered [see 3.2, 3.6, 3.10]. What seemed to have changed during this period was the public's acceptance of risk in light of its perceived benefits. Thus it is evident that, by the end of the decade, the public were much less tolerant towards the technology and much more reticent to allow its wide scale use. Indeed, a large number were sufficiently concerned so as to become politically active about it, marking what the media referred to as the 'public backlash' or 'crescendo of consumer concerns' [see 3.10.1]

[5] *ibid,* p 7.

Many previous backlashes against large-scale technologies had been associated with catastrophes or disasters. For instance; the Minamata Bay poisoning; the Three Mile Island meltdown; the Cuyahoga River fire; BSE; Foot and Mouth disease; are just a few examples of man made disasters which led to social uprising against technology and calls for reform.[6] These events shocked people worldwide and pervaded the public psyche. Gene technology has gained no such infamy, there have been no epidemics caused by it, no environmental devastation created by it. What then caused public intolerance and backlash?

In the blame society the public tends to view technocrats as the progenitors, and technology as the source, of risk [see 5.2.2]. Novel technologies are unlikely to be seen as unique but as part of the continuum of scientific and industrial advancement. As can be seen from the discussion about the development of risk communication [see 11.2-11.5] the public can be said to have become increasingly wary of the benefits of large-scale technologies. There has also been a marked decrease in trust of technocrats to adequately attenuate risks and act in a beneficent manner over the past half century in particular. What is perhaps most important in contextualising the reaction to gene technology is the impact of the various incidents relating to food and agricultural production prior to its commercialisation. These served to transpose the public fixation with risk from heavy industry onto agricultural and food manufacturing technologies.

13.2.1 IGNORING THE WARNING SIGNS

International food scares, particularly BSE [see 3.2.4] undermined the trust that many people around the world had in novel food technologies, those who promoted such food and those who regulated it. The result was apprehension about the safety of foods that went through 'unnatural' production processes.[7]

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[6] See generally: Erikson K, *A New Species of Trouble: Explorations in Disaster, Trauma and Community*. Norton, New York 1994; Turner B, Pidgeon N, *Man-Made Disasters*, 2nd ed. Butterworth-Heinemann, Richmond, 1997.

[7] Surveys conducted before the BSE outbreak indicated that only twenty five percent of Britons were opposed to GMOs. A poll following the scare indicates that only one percent those surveyed in the U.K. believed that GM foods offered any benefits whatsoever.see Ed., 'Food For Thought.(Genetic Modification Of Crops)', *The Economist* (US) 19/6/1999, p19.

Furthermore, the revelation that governments and corporations had colluded to suppress certain risk data meant that many people became increasingly assertive about their 'right' to information about the ingredients and manner of manufacture of food they were eating. Thus, we can see organic food moving from a small niche market into the mainstream supermarkets around the world following these food scares.[8] Food had come to the attention of the blame society and thereby subject to the scrutiny and scepticism previously experienced in the environmental, nuclear and industrial debates. It was into this highly charged political environment that gene technology was introduced.

Those promoting the gene technology tended to overlook consumer suspicion about novel foods prevalent at the time. They seem to have viewed 'food scares' as individual incidents and assumed public discontent was directed towards specific manufacturing processes rather than against the industry as a whole. Furthermore, they neglected realise that there were some very simple features of this technology which made it a candidate for a high risk perception in the community. That is, gene technology:

- was novel and unfamiliar;
- had public health implications, insofar as it affects consumables and the environment – as a result it has a direct impact on individuals and the community; and
- was generally a manufacturing process and hence it was hard if not impossible to avoid, placing it outside most people's direct control.

Starr had pointed to such factors early in the stage 1 model of risk communication as indicia of high risk perception and low acceptability threshold towards a technology. I would also point to some other factors that I see as pertinent to the acceptability threshold of a new industry such as gene technology.

> *Commercial Versus Personal Benefits.* In chapter 2 I highlighted that first generation GMOs are designed to provide agricultural and commercial benefits. It is primary industry who gains from pest resistance and seed

[8] Anon., 'Organic Farming Enters the Mainstream,' *Nature* 6985:**428**:783

companies who benefit from trait control technologies. The general populace is unlikely to back a product which creates public health risks but which does not benefit them directly.

Internationalisation. Although Australia has a thriving research community, the majority of gene technology products have been produced elsewhere by multinational corporations (in particularly from the US). It is hard for Australians to 'own' such products when the corporations behind them are clearly from elsewhere and acting under international not local agendas. Indeed the opposite tends to be true in the blame society. Gene technology was perceived as being too heavily influenced by international agents and international agendas rather than by the Australian community itself. This was the primary concern of the Lay Panel of the *Consensus Conference*, which decried the fact that 'multinational corporations have been allowed to decide the fate of GMOs'.[9] Had the technology been invented here, or been owned by Australian companies perhaps this might have been different.

No Counter Community. As a new product gene technology had no 'traditional' industry that might react to counter opposition to it. Take for instance the forestry debate, which has been a dominant political issue for several decades now. A great deal of opposition the logging of old growth forests exists in the Australia. However, calls for the cessation of the practice have met with opposition of their own. Traditional forest working communities argue that to cease old growth logging will mean lost jobs, lost income and the loss of tradition. These groups have formed into a strong and vocal counter lobby, backing industry and becoming politically active.

Novel technologies are simply incapable of tapping into large portions of the community in this way because their cessation will rarely mean the loss of jobs, income or tradition. Although farmers or agriculturalists might have lost a potential revenue earner, their livelihoods and way of life

[9] Lay Panel Report, *op cit* 115, p 6.

> were not at risk. These communities are unlikely to react with the energy and activism of those who suddenly perceive themselves to be at risk from a new technology.

There was, then, sufficient warning that gene technology would create public opposition and play on the underlying psychosocial fears ingrained in the blame society. This is not merely evident in hindsight. Outside of the vast body of academic risk literature, various organisations, including the Federal Government, forewarned of the potential for a public backlash. Indeed, the House of Representatives flagged most of the abovementioned points as early as 1992 as the basis for legislative intervention [see 3.1.2]. Such factors were, however, largely ignored. Instead, there was a tendency for proponents to treat genetically modified organisms and foods simply as new products, which they expected would eventually captivate the market.[10] They appear not to have considered that the public might have a higher risk perception than they themselves did or indeed be any less excited about its envisioned benefits. The result was that little or no consultation was undertaken with the public about the acceptability of gene technology and most people only became aware about it after the press revealed that genetically modified products had been in the food supply for 'some time' [see 3.4].

13.2.2 THE WAR ON ERROR

If you do not ask what is causing someone to display a certain type of behaviour (anger, anguish etc) then you are left to make assumptions about their behaviour from your own experience of what caused you to act in that way. In some cases you may make the right assumptions, but in others you may mistake the cause of that behaviour altogether. I would suggest that such a mistake occurred with the introduction of gene technology. Rather than consult with the public, technocrats made their own assumptions about what was motivating public resistance to gene technology. Such assumptions were naturally subjective and formulated within a

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[10] Pollan M, 'Playing God In The Garden', *New York Times Magazine*, 25/10/1998, p 44 ; Newton J, 'Consumer Manipulation and the GM Food Debate When the Experts Say Trust Us, It is Time to Worry About the Future of Farming', *Sydney Morning Herald*, 10/4/2000, pA3.

scientific, depoliticised and reductionist technocratic worldview. Technocrats – despite the lessons learnt over the past three decades – looked to numeric risk as the primary determinant in the equation, because that was what *they* were primarily concerned with.

Hence, proponents began down a path dictated by false assumptions, adopting management and communication strategies that focused on their own worldview, but not always the worldview of the various publics interested in gene technology. These strategies formed part of what proponents came to label a 'war on GMO propaganda' or 'war on disinformation' [see 3.2.4] – or to put a more contemporary slant on it a 'war on error'. The war on error can be seen as taking on three increasingly aggressive stages:

1. the consumer oriented, public relations, 'trust us its safe' approach;
2. a campaign to discredit opposition to gene technology or the 'don't trust them they're luddites' approach; and
3. the policy/regulatory oriented, substantial equivalence lobby – or 'don't trust yourself you don't need to know' approach.

Trust Us It's Safe. Because proponents assumed that public concerns were motivated by 'ignorance' and 'misunderstanding', their initial strategy centred around conveying what they believed to be the correct message as broadly as possible. Risk communication was constituted of little more than public relations campaigns, promotion and advertising to convince the public they had 'nothing to worry about' and that the technology was the 'way of the future' [see 3.2.4, 3.7].

Stereotypical stage 1, 'trust us its safe' campaigns did not placate the public but instead thrust the technology into the public domain in a way that small stakeholder groups had been unable to.[11] The fact that companies were trying so

[11]For instance, British biotechnology companies undertook a concerted advertising campaign to promote the benefits of GMOs, including their beneficial impact on human health. In a country particularly sensitive to risk information following the 'mad cow' scare the publicity had the opposite affect of what was intended. Instead of creating support for their products the campaign actually caused an even farther reaching consumer dissent, as people who had not heard of biotechnology became aware that they were being sold mysterious and seemingly unethical products without their consent. see Anon., 'Food For Thought', *The Economist* (1999), 8127:**352**:19.

hard to convince people that something they hadn't heard about needn't worry them immediately set off alarm bells among many in the community. These campaigns made people aware that: the technology would affect their food; someone had decided it was safe; and they had little choice but to accept it. Instead of being premised on consumer choice they were designed to tell the public that someone else's choice was the right one – an adventurous gamble in the blame society.

Don't Trust Them They're Luddites. The initial attempt to convince people that the risk decisions being undertaken on their behalf were correct and safe failed. Yet proponent held to their assumptions that public concern could be quelled with numeric data and that certain parties were intentionally misrepresenting that data, thereby fuelling dissent. Subsequently they turned their attention towards discrediting those they saw as propagating the 'disinformation' responsible for the public backlash. Those who publicly opposed gene technology were painted as 'luddites' and 'anti-capitalists', 'fear mongers' and 'pig-headed opposition'.[12] One proponent's response to the Consensus Conference [see 3.6] was indicative of much of the rhetoric aimed at those who tried to foster public discussion and debate on gene technology:

> [s]care campaigns show us the limits of democracy … The recent consensus conference on gene technology was anti-science, anti-knowledge. ... The final communiqué shows that the conference was a waste of time. The participants were at best naïve.[13]

In other words, any decision – whether made by a federally sponsored representative body or not – which did not accord with what 'experts' believed to be right is simply wrong and premised on ignorance. What is also very interesting from the statement is how it portrays the ongoing narrow world view of the pro gene technology lobby. The author sees the issues as purely relating to 'science',

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[12] see for example: Ed., 'Modified Food Fear', *Herald Sun*, 16/10/99, p 19.; Ed., 'Biotechnology: A Challenge, Opportunity', *Courier Mail*, 30/10/1999, p 22; Crawford D, 'Cash Crop Worth Risk', *Tasmanian Country*, 28 /7/ 2000, p 001

[13] A comment by the Executive Director of the Australian Supermarket Institute extracted from, *Gene Technology & Food*, Report of the National Science & Industry Forum, April 1999, Australian Academy of Science, Canberra, p 9.

'knowledge' and numerical risk, even though the final communiqué placed just as great, if not greater emphasis on the social, legal and ethical implications of the technology. He is clearly frustrated by the continued rejection of the technology and suggests the public should be disengaged from the process altogether. Yet, the author is not only attacking a critic, he is attacking the public themselves because the consensus conference was meant to be representative of the public as a whole. Dismissive and derisory statements such as this did little to bridge the gap between 'experts' and lay people and ultimately came to be seen as an attack on the public's right to question science and the uses to which it was put.

Don't Trust Yourself You Really Don't Need to Know. Attacking critics did little to undermine their message. In fact, it created solidarity among opposition groups and anger among a greater proportion of the community. However, technocrats continued to view the cause of such discontent as a combination of misinformation and ignorance rather than as a consequence of their own outmoded risk communication approach. To them, the view that genetically modified foods were somehow different to conventional foods was ultimately ignorant because numeric risk data showed they were not. Thus, the new front on the 'war on error' became the quest to remove information about genetically modified ingredients from food labels altogether.

The concept of substantial equivalence was discussed at 3.2.4. Substantial equivalence was justified on a number of grounds: the costs of labelling; the resources required to segregate products; and indeed as a response to the public backlash to gene technology. Yet opponents viewed it as something much more black and white, an attempt to limit people's 'right to know' about what was in their food – at that time a particularly sensitive issue. This was not helped by the fact that at the same time proponents were lobbying in one arena to have products labelled substantially equivalent they were arguing in another that the same products were 'substantially different' enough to warrant patenting.[14] Substantial

[14] As one author notes 'Paradoxically, on the one hand, the food industry argues that transgenic foodstuffs are not sufficiently different from their conventional counterparts to require labelling. But conversely - oxymoronically? -they are deemed unique and are therefore patentable. A case of having two bob each way?" Ripe C, 'Tricky keeping track of genes in your beans', *The Australian*, 3/3/1998, p 14

equivalence – legitimate scientific method or not — appeared little more than a 'GMO laundering strategy' to mix GM foods into the conventional market. This played on existing fears about 'cover-ups' of novel foods and technologies and the removal of the public from the locus of control over public risks.[15]

That the suppression of information about GMOs and GMO products was driven by more than simple market economics was proven when a series of 'cover-ups' actually occurred Australia. The Aventis breach [see 3.12] revealed that local councils, neighbours and even the farmers who were growing GM crops were not being told about what they were trialling. When commercial crops were discovered in Tasmania, despite the existence of a moratorium there [see 3.16], it became clear that both industry the Interim Office of the Gene Technology Regulator (Interim OGTR) were willing to suppress information about gene technology from even state governments. The Monsanto incident [see 3.8] showed that even where contamination was detected and reported to the Interim OGTR they were not made public. Such incidents, in combination with reports of cover-ups elsewhere in the world, indicated that a conscious effort was being made to 'keep the public in the dark'.[16]

By choosing secrecy over engagement in response to the backlash, both industry and government indicated they were unwilling to work with those affected by risk or include the public in decision-making. In the end, it was this secrecy and lack of transparency that created the most trenchant opposition to gene technology. Consequently, this most aggressive stage in the war on error proved the most counterproductive, fuelling community dissent and fortifying opposition to its introduction.

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[15] A perception that was propounded by the fact that much of the drive for substantial equivalence was played out at the international level. Because of this substantial equivalence seemed a policy developed without much domestic input.

[16] Stott-Despoja N, 'Matters Of Public Interest: Genetically Modified Crops', *Senate Hansard*, 5/5/2000, p 13384.

13.2.3 A GENERAL MISUNDERSTANDING

Throughout the war on error there was a definite attitudinal division between – as the Director of Monsanto so aptly put it - 'us', 'the experts' and 'them' the 'antis'.[17] Perhaps such an attitude arose because, prior to its commercialisation, gene technology was a discrete discipline, creating little public interest. The few in the community who were aware of it tended not to be actively involved or engaged with it. It seemed a prospective science and therefore most people were happy to leave it in the hands of the scientists and technocrats interested in it. Of course, commercialisation changed this. No longer did the risk decisions taken by those in control of gene technology affect a small number of people or small confined regions. Commercialisation meant that such risk decisions affected all those who might consume genetically modified products or live within the environment that GMOs were released into. The floodgates were now open and gene technology and the risk decisions surrounding it became the concern of the community as a whole.

Those who had been in control of gene technology prior to its commercialisation appear to have been ill at ease with the sudden widespread interest in it and reluctant to relinquish their decision-making monopoly. The time and resources invested in gene technology research and development goes some of the way to explaining why some may have been reticent to suddenly share control over it with others. It might also be explained as the product of a community who were simply unused to public exposure and uncomfortable with the idea of engaging with that public. Nor can it be denied that there was a certain degree of intellectual arrogance in some quarters, something later admitted by leading industry members themselves.[18]

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[17] *ibid.*

[18] "[p]roponents of GM foods trumpet their benefits and cry foul over misinformation spread by opponents of GM foods … But they lost the battle for the hearts, and minds, of consumers very early in the debate, mainly through a combination of arrogance and ignorance" The director of Agribusiness Australia in *Australian Farm Journal*, July, 2000 quoted in Goode A, 'Visit To a State-Backed GM Trial Points to Need for Public Debate', *The Advertiser*, 12/10/2000, p 18.

Whatever the reason, the retention of control by a select few tended to reinforce the traditional technocratic hierarchy between those making public risk decisions and those exposed to them. Such divisions played on existing public fears about technology, risk and decision-making and served to heighten anxiety about gene technology. Yet, because those in control did little to actively engage with the public, they mistook both the basis and extent of such concern. They assumed that the public was merely mistaken about the numeric risk the technology posed. Later it became clear that there were a plurality of concerns and that in fact much of the anger derived from not being engaged with in any real or substantial way.

Adopting false assumptions about what was driving public opposition led to the implementation of misdirected and incomplete strategies. When the initial strategies failed they were replaced with increasingly complex and aggressive tactics, all of which were premised on the same false assumptions about what the public wanted and needed to hear. Yet these campaigns continued to treat the public as a singular entity rather than realising there are diverse 'publics' and they remained decidedly unidirectional in nature. Unidirectional communication, by definition, proscribes the amount of information that may flow back to a risk manager that might indicate why the position adopted is failing to win support. In the absence of such information, technocrats held to their assumptions about the basis of public concern and hence the resistance appeared to them to be unfounded and misdirected.

The inability to make the public understand risk data caused a great deal of frustration among gene technology proponents. This, in turn, lent to increasingly aggressive promotion of gene technology and more vitriolic responses to objectors [see above, 'Don't trust them']. Finally that frustration led to proponents distrust in the public's ability to make reasonable decisions at all and they tried to exclude the general public from risk analysis altogether [see above, 'Don't trust yourself']. Such reactions merely served to drive a further wedge between the public and technocrats as the apparent power differential became more overt. The result was a self-perpetuating cycle in which each party (the public and technocrats) became less willing to listen to the other and more frustrated with the other's refusal to listen to them.

13.3 A LACK OF FORESIGHT

Objectors to gene technology have sometimes asserted that the public was 'kept in the dark' about gene technology in a deliberate attempt to introduce it surreptitiously and without people's consent.[19] Whether or not this is true is questionable, particularly given that the fierce international competition in agribusiness is less than conducive to the type of intimate mutual collaboration needed to affect such a scheme. I would suggest that it is that very market competition which contributed to the marketing of products without public debate.

Whilst it would be laudable if the industry voluntarily restrained market entry until public had acquiesced to their products, the reality is that companies owe their primary duty to their shareholders. For most modern companies this obligation translates to maximising profits, minimising restraints to market and exploiting systemic gaps or loopholes. Gene technology took a great deal of time and research before it became at all commercially viable. Indeed, the uncertainty about its market potential made attractive initial funding difficult and investors particularly nervous.[20] When that research finally translated into commercial products there was a general rush among genetics companies to realise returns on research investment and dominate a completely new market. [21] If they hadn't, their competitors most likely would have. The fact that companies did not stop to think about the public reaction is perhaps understandable in such circumstances.

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[19] "it is a 'basic contravention of citizen rights' not to label food and give consumers choice about whether to buy it", Dunlevy S, 'When a Sweet Tomato's Not Really a Tomato', *The Daily Telegraph*, 30/7398, p 9 ; `"It's not a safety issue we're talking about, it's a question of whether people have a right to know what they're eating … in most cases now we don't know the components of what we're eating", Watt A, 'Future Food', *Courier-Mail*, 29/7/1998, p 28 ; see also Ed., 'Genetic Crops Reaping Public Distrust', *Herald Sun* , 19/11/98 , p 41 ; Reeves E, 'Messing With The Harvest', *The Mercury*, 9/6/1999. p 39 ; Ragg M, 'Time to Find a New Recipe', *Sydney Morning Herald*, 25/06/1999 ; Ed., 'Genetic Crops Reaping Public Distrust', *Herald Sun* , 19/11/98, p 41 ; Cummins K, 'GM Debate May Leave Sour Taste', *Australian Financial Review*, 20/06/2000, p 58 .

[20] Whitehead G, 'Early stage and seed financing for biotechnology start-ups: A UK perspective' (2003) *Journal of Commercial Biotechnology*. 3:**9:**242

[21] Harl N.E et al, 'The StarLink Situation', Biotech Info Net, Working Document, Rev. 10/25/00, 2000 : <http://www.biotech-info.net/0010star.PDF> (12/12/02).

Hence, I would argue that blame lay not so much with industry but in the lack of governmental intervention early on, indeed prior to commercialisation.

13.3.1 GENETIC MANIPULATION ADVISORY COMMITTEE

By the time gene technology was introduced the Government was well primed for public distrust in novel technology. By the 1990's discussions about risk peppered local, national and international politics and risk communication theory had moved into its third stage. Australia had signed on to Agenda 21 in 1992, which forewarned of the need to communicate with the public on the commercialisation of gene technology [see 11.5.2]. The Government itself had released the NHMRC report in 1994 [see 11.6]. That report represented some of the most advanced risk communication policy anywhere in the world and it emphasised the need to integrate risk communication into risk governance to avoid public distrust of science and technology.

Despite the forewarning and despite the existence of domestic policy encouraging deliberative risk governance, the Government came 'lately' to the issue of participatory communication about gene technology. Whilst GMOs were in their developmental phase, and used mainly overseas, the small scientific Genetic Manipulation Advisory Committee (GMAC) was sufficient to oversee the research process. During this period there was little concern about the GMAC's existence, structure or decisions among the Australian populace. Although several inquiries and reports had been undertaken recommending that a regulatory system be put in place [see 3.1,3.1.2,3.3] there was little political or regulatory preparation for the looming commercialisation of the technology. This meant that when the use of GMOs became 'actual, immediate and present' in Australia, the system that was in place was ill-equipped to respond to community interest and concern.

The GMAC was a body unable to deal with the broader public debate that occurred with the commercialisation of gene technology. This was not so much due to internal flaws but rather because the Government had not provided it with

the right tools to engage with the broader community or provide a platform public deliberation. It was a small body, with little administrative infrastructure.[22] Hence, communication and reporting tools such as its website were not very user friendly nor updated on a regular basis.[23] Furthermore, the committee was comprised of scientific and industry experts[24] and the Government had not seen it necessary to have representation from public, consumer groups, ethicists or any other key sectional interests.[25] Finally, the GMAC system was voluntary; limiting the amount of information that it could obtain without the consent of those it oversaw.[26] The lack of any statutory powers obliged the body to 'court industry' in order to encourage companies to provide all relevant information, particularly because risk data is a sensitive corporate issue.[27] This often meant that the GMAC had to promise to keep risk data relating to commercial trials and any decisions it

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[22] Wynen E, '*Genetic Engineering And Agriculture: Australian Farming At The Crossroad*s, Report of the Economics, Commerce and Industrial Relations Group, Commonwealth Library, Canberra, 1999.

[23] Whilst the site did provide a listing of non commercial-in-confidence trials, there was no clear directory of crop trials. Moreover, it did not allow the user to filter trials from a specific location or of a specific crop type. No crop lines were listed, making it hard to differentiate between different varieties of the same crop type. "The extent of experimental GM crop trials currently under way in Australia is uncertain. The Genetic Manipulation Advisory Committee's (GMAC) web site provides a list of crops being trialed, and has listed the location and size of some trials, but the exact lines (specific genetically modified crops - eg potato line RBMT15-101) are not stipulated. GMAC also lists current proposals separately. GMAC has guidelines for crop trials, but different conditions apply depending on risks involved for each successful application", Wynen E, *Genetic Engineering And Agriculture: Australian Farming At The Crossroad*s, Report of the Economics, Commerce and Industrial Relations Group, Commonwealth Library, Canberra, 1999, p 234.

[24] Many of the Committee members were either existing or ex-industry members Some criticised it on these grounds as having being 'captured' by industry "The Government is being advised by the biotech industry. The only regulatory body, the genetic manipulation advisory committee, is comprised of people mainly drawn from the biotech sector. About half of its members are employed by the organisations that have proposals before the committee, so they are watching themselves. Another three of those 14 people are retirees of those same organisations. So you have a stacked committee of people who you could argue are committed to this technology going ahead." Ripe C, 'Secret Ingredients', *The Australian,* 13/5/2000, p 12.

[25]Office of the Gene Technology Regulator 'Voluntary System, Background & History', Commonwealth of Australia, OGTR Website, <www.ogtr.gov.au/volsys/background.htm> (28/12/02)

[26] The Interim OGTR admitted the GMAC had a 'limited capacity to access documents or premises or to investigate matters unless the entity concerned chooses to cooperate'. Submission No.77, p.169 (IOGTR), to the Senate Committee :
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[27]Aventis highlighted this when it stated that they saw the GMAC as having 'no power to compel [participants] to do anything they wished not to do'. Submission No.61, p.9 (Aventis), to the Senate Committee :
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

made relating to that data confidential.[28] This of course had the potential to make the body appear secretive.

In all these respects the GMAC system was simply inadequate and incapable of dealing with the broader ethical, social and legal debate surrounding gene technology. The lack of a real regulatory framework left the door open for companies to act in whatever manner they saw fit. Where GMAC did try to guide corporate behaviour, its focus was narrow and technically driven. It didn't consider the ethical, legal and social risks of the technology because no one qualified with such expertise was represented. Public concerns were not represented because there was no real and substantial avenue for the public input into the work of the committee. In the absence of such a forum, members of the public formed their own lobby groups [something discussed below see 13.3]. Hence, the Office of the Gene Technology Regulator (OGTR) admits:

> [f]rom a community perspective there was inadequate consultation and transparency in relation to decision making and a lack of confidence in the effectiveness of the control system.[29]

I argued above that the behaviour of industry can, in some way, be explained by the competitive market into which gene technology companies found themselves, and indeed the fact that many of these companies had not interacted with the public before. The Government's failure could also be attributed to a lack of foresight in realising the speed of commercialisation or the impact of international events; although I would suggest this is a little less excusable. The fact that it was six years from the introduction of gene technology until legislative intervention indicates that this area may not have been initially considered the highest

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[28] In most cases industry was sensitive about the release of risk data, either because of its commercial nature or the negative public impact it may have had. However, the GMAC needed this information to operate effectively.Whilst it provided information on its web-site regarding registered trials many were precluded from publication by commercial-in-confidence provisions. Also GMAC was further constrained in revealing breaches of the scheme such as the lack of notification of the use of GMOs by third parties (non volunteers) see Office of the Gene Technology Regulator Quarterly Report September, AGPS Camberra, 2000, p 1.

[29] Office of the Gene Technology Regulator 'Voluntary System, Background & History', Commonwealth of Australia, OGTR Website, <www.ogtr.gov.au/volsys/background.htm> (28/12/02).

regulatory priority. Furthermore, the existence of substantial government policy recommending the adoption of effective risk governance with respect to novel technologies also indicates that, whilst forewarned, the Government was reluctant to regulate immediately. In the end, this delay proved more detrimental to the advance of the technology because it created an environment of mutual distrust between the public and those promoting the technology.

13.3.2 AN ISSUE OF TRUST

Because the GMAC was not equipped to deal with public interest in gene technology, few in the community were aware when the first products were commercialised or the first crops were trialled. Indeed, the GMAC's lack of communication with outside groups was so prevalent that even state governments were unaware of crop trials occurring within their own jurisdictions [see 3.16]. As noted previously, much of this secrecy was promoted by industry who were less than willing to publicise their dealings. As a result, the public often learnt about gene technology through media exposés. In such circumstances the existence of a Government 'watchdog' such as the GMAC did little to allay public concerns. In fact the existence of the GMAC agitated matters because the body seemed to have been fully aware of both the 'secret trials' and 'secret breaches'. This gave the appearance of Government knowledge of, and therefore collusion with, industry's attempt to introduce the technology 'by stealth'. Democrat leader Stott-Despoja described the wave of community concern as;

> not an issue of lack of scientific understanding but more a distrust of non-consultative government regulation, secrecy and use of alternative technologies. This is interpreted by people, by consumers and by community members as trying to pull one over the local community.[30]

This lack of trust was voiced at the Consensus Conference, which heavily criticised the GMAC for, *inter alia*, its lack of transparency and public involvement.[31] Russel notes that the Lay Panel was so dismissive of the agency as

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[30] Stott-Despoja N, Matters Of Public Interest: Genetically Modified Crops, *Senate Hansard*, 5/4/2000, p 13384.

[31] We as a panel believe that the regulatory and advisory bodies in place (e.g.ANZFA, GMAC, etc.) are currently not serving community interests. ... It appears that current regulation is too narrow in its focus on

a 'public' body that it didn't bother to invite it to defend itself against the criticisms.[32] Russell believed that:

> [t]his was apparently a result of mistrust the lay panel held for government bodies … which came under heavy criticism, must clearly lift their game, both in their process and transparency. Whether their bias is real or perceived, the community cannot have confidence in a regulatory process if it does not trust the regulatory bodies responsible.[33]

Hence, in the debate over the form, powers and duties of the OGTR, all sides of the political divide called for transparency and public participation to be built into the new system in order to re-establish community trust [see 3.18]. The most unfortunate side effect may be that the damage caused by the earlier scheme will have residual effects on the continuing operation of the OGTR.

13.3.3 A 'PROXY' STAGE 3

Ironically, the gene technology industry did not, in the long term, benefit from the initial lack of legislative intervention. Instead of dominating the food and agriculture market, as it might have expected to, the industry found itself subject to a social backlash which saw products pulled from the shelves and plants pulled out of the soil (both wittingly and unwittingly). Government too suffered from the backlash, attracting a great deal of internal and external criticism and indeed putting it behind what it saw as an international race to be at the forefront of agricultural research. Yet the impact of this dissent was wider than mere market failure, it led to the creation a created a 'proxy' stage 3 environment. By this I mean that, in the absence of a structured regulatory system impelling dialogue, the

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science … Government should embrace a commitment to bring together all stakeholders In short, government … should act as a facilitator rather than an arbitrator.

to talk to each other to reach agreement on mutually beneficial solutions … Decisions are being made too quickly and with a lackof public consultation. The decision making process is currently inaccessible and open to bias." Lay Panel Report, *op cit* 115, p 6.

[32] Russell W, 'Letting the Gene Out of the Bottle' (1999) *Australasian Science*; 4:**20**:30.

[33] *ibid.*

community itself created a forum in which debate and deliberation were unavoidable. This was marked by the rise of stakeholder groups campaigning about gene technology as well as a dramatic increase in media scrutiny [see above]. Through these avenues various publics *forced* greater debate, greater involvement and broader deliberation among organisational actors. They *made* decision makers take into account the concerns of various publics.

Thus, even where public input is not sought, the public will, if sufficiently interested and motivated, make its voice heard and can directly influence public policy. The resulting proxy stage 3 environments served as a platform upon which various parties could call for process legitimacy in the form of legislative intervention (stage 4). This included industry [see 3.3] who by this stage realised that regulation was needed to address community concern and reignite trust in the technology and risk decisions relating to it [see 14.4.2]. The down side for gene technology proponents was that this proxy stage 3 environment arose very much in response to the 'war on error'. The result was that by the time a platform was created which allowed debate and discussion, many in the community felt negatively towards the industry and the technology. As one Opposition member argued, 'market driven multinational corporation[s]' had proven themselves the wrong bodies to be the final arbitrators of what 'is good or bad in a living organism'.[34] Similarly, the Senate Committee recognised that the introduction of the GTA necessary because 'industry cannot be relied upon to be sufficiently rigorous and objective in evaluating risk and implementing appropriate management strategies'.[35] Apparently non-regulatory governmental agencies could not either.

13.4 CONCLUSION

By the end of the century there was a marked negative reaction among much of the community. As explained previously the 'general', 'informed' and interested

[34]Murphy J, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29 August 2000, p19544.

[35]Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, 2000, para 3.15.

publics all expressed high risk perceptions and were reluctant to allow gene technology in 'their backyard'. Depending on whose side you are on, such a backlash can be explained by fear, anger, mistrust, ignorance, arrogance, technocratic imperialism or social intransigence. Yet, the reality is that the real seed of the public dissent lay in the failure to implement open, transparent and inclusive mechanisms to ensure the public interest was served from the outset of the technology's commercialisation. Instead, gene technology became the subject of a disastrous and outmoded public relations campaign that went horribly wrong. So, what can be learnt from this experience from a regulatory perspective?

Repeating Failures. Foremost, the experience indicates that despite previous lessons and despite the existence of best practice, risk communication failures are easily repeated where there is no regulatory imperative to do so. Gene technology has reinforced that measures to ensure participatory risk analysis are unlikely to be voluntarily adopted by the corporations in control of new commercial technologies. New start-ups can be quite naïve when it comes to risk communication and old companies can prove quite bullish when trying to dominate a new market. The fact is, that there was a regulatory lacuna in existence at the time of gene technology's introduction and some companies exploited it. That is how the market works.

Industry does not operate in a vacuum but within the confines of the laws and corporate structures established by government. Furthermore, industry often acts at the behest of government or with its financial, legal or technical assistance. Certainly this was the case with gene technology, with the Australian Government providing great deal of political and monetary support in the form of funding and through the Biotechnology Strategy. Where government negates to do one (restrict) or the other (promote), it tends to attract criticism and censure from different sides of the political divide. Either way, the public *expects* the Government to be involved in corporate behaviour and therefore sees it as partly, or equally, responsible for that behaviour.

This contemporary role of government as funder, promoter and even partner of science and industry can tend to conflict with its traditional function of legislator.

In promoting industry it may seem more attractive to a government not to intervene in the corporate behaviour, nor create proscriptive legislation because this can be seen as inhibitory to the path of new products to market. Subsequently, it may seem more attractive to government (as well as to lobby groups and industry) to take a generally hands off approach to legislating until the technology has found its feet. Yet, if we take gene technology as an example, it becomes clear that, rather that benefiting emerging industry, regulatory inaction can in fact stymie the long term success of a new technology and greatly undermine the trust that the public has both in that industry and the government bodies responsible for it. Rather than ease market entry regulatory inaction led to a war between industry and the public, the very bodies that the Government is attempting to represent and protect.

I would argue that not only does the Government have an obligation to intervene on behalf of the public in the blame society, but also on behalf of the very industry it seeks to promote and support. I am not suggesting it is the Government's role to intervene in any form of corporate behaviour nor every type of scientific or technological endeavour. However, the commercialisation of novel technologies – in particular those that create broad ranging social, ethical, public health or environmental risks such as gene technology – do necessitate some form of legislative intervention. This intervention needs to be real and substantive, creating institutional mechanisms that oblige all aspects of the risk analysis paradigm, particularly risk communication.

Involvement at the Outset. What also becomes evident from the experience of gene technology is that legislative intervention is necessary from the *outset* of commercialisation and if possible, prior to it. I accept that it is a rather cyclical argument to state that because proponents failed to consult with the public they did not realise that the public wanted to be consulted with. Yet, neither should this be an acceptable excuse, particularly for ongoing complacency and inaction. Enough academic and public policy exists to indicate that excluding the community from risk analysis is counter productive and causes dissent. It cannot be denied that, a lack of consultation was one the primary causes of the public backlash against gene technology. Had a participatory approach been adopted

earlier, much of the anger and resentment towards the technology and its proponents might have been avoided.

If we are to learn from such mistakes we must ensure that risk communication occurs from the outset of each new use to which the technology is put. This is particularly true of gene technology which has a variety of commercial applications and which may interact with different environments in unique and unforseen ways. Without such consultation risk managers are effectively cutting off their primary source of feedback. The result is incomplete risk identification, undermining the entire risk analysis processes and more often than not aggravating those who are at risk.

True Dialogue. What may also be learnt from the war on error is that unidirectional risk communication strategies *do not work,* no matter how complex or how forcefully they are pursued. What can be seen above is the result of adopting a completely stage 1 approach to risk communication. Unidirectional communication created false assumptions about the basis of public risk perception in the minds of those for whom it is imperative to properly understand it. Without a complete understanding of public concerns, hazard identification, the cornerstone of risk analysis, was incomplete. This meant that communication and management strategies built upon it were ultimately lacking and indeed misguided.

The various strategies adopted as part of the war on error to quell public disquiet did exactly the opposite; the more aggressive they were, the more aggravated the public became. The more money and effort that was put into reassuring people of the safety of the technology, the less trusting people became of it. As people perceived they were being excluded from dialogues about risk they became more active and more motivated in opposition to what they saw as the source of risk. A stage 3 process is inevitable in such circumstances, whether or not it is a true process or a ‘proxy’ one and whether it is established with the consent of decision makers. In 1995, a single lobby group may not have had that much influence on Governmental agendas. By 2000, the collective risk perceptions of the various groups described above could not be ignored.

True Representation. The heart of the risk dilemma is the question of control, specifically who has the control to make risk decisions on behalf of the greater populace. We can see this struggle played out in the war on error as those bodies in control of gene technology struggled against those who were the recipients of it. Perhaps the attitudinal separation between 'experts' and the 'public' will remain ever entrenched in the technological endeavour. However, I would contend that such divisions must be overcome for effective risk governance to occur. Whilst experts occupy a niche within the community, they are not separate from it. Exposure to public risk is a shared experience and therefore decisions about it should be shared too. Whilst some parties may have a greater interest in that risk or possess greater expertise with respect to it, none should be allowed to dominate the agenda.

I am not denying that public involvement in risk governance must of course be approached with a certain degree of caution. People do overestimate risks, they do have 'knee-jerk' reactions to technology and they can be motivated by vested interest. They cannot ever have the level of scientific expertise that scientists and technicians trained in a specific area will have. Yet, this is not a reason to exclude them from the process. If that was the case, then regulatory officials, parliamentarians and legislators – none of whom have the requisite level of expertise – would be precluded from making decisions about complex technology.

What we must also face is that the general public may reach decisions which do not accord to that of the experts or the political elite. I would suggest that this is one of the most substantial fears underlying the general reticence to effect true deliberation. However, we must seriously question whether or not, in a democracy the people have the right to choose what some, for example technocrats, view as the worse alternative. If we say no then we are going down a dangerous path – one in which someone or some group will always have the right to veto the public choice with their own version of the truth. Gene technology should teach us that the blame society is less than willing to accept such a scenario. The community is simply too sceptical of institutional actors to allow them to dictate how public risks should be dealt with.

Regaining community trust in novel technologies requires legislators and technocrats trust the public to make informed decisions on their own behalf. This requires placing representatives of communities affected by risk at the heart of regulation and encouraging a dialogue about the broader aspects of that risk. It means ensuring that participants are informed by technical experts but not dominated by them. Most importantly, the risk governance process needs to be designed to ensure that those making risk decisions are never ‘at war’ with those at risk.

PART IV

DELIBERATIVE RISK GOVERNANCE THEORY IN PRACTICE

14

PUBLIC CONSULTATIONS TOWARDS THE GENE TECHNOLOGY ACT : FROM PROMISE TO PRACTICE

The previous chapter examined the 'micro-evolution' of risk communication practice with respect to gene technology. Early failures to adequately involve the public in decisions about the use of gene technology led to the strengthening of sectional interests and a social backlash against the technology and those overseeing it. In this chapter I look at what the Government did to remedy that situation.

I argued previously that regaining public trust demanded that legislators place communities affected by risk at the heart of the risk governance process and encourage a dialogue about the broader aspects of risk. Yet because the Government came lately to the concept of deliberative risk governance there were no mechanisms through which such a dialogue could be achieved. Consequently, the first step towards regaining public trust was to include them in the reform of those structures perceived lacking.

Deliberative risk governance recognises the need for integrative and deliberative communication about the very foundations of risk analysis and the risk governance regime that implements it. Thus, the following discussion relates to how the Government moved from a 'proxy' stage 3 process into a real one by becoming involved in and responsible for dialogues with the community about

gene technology and how it should be regulated. Again, it is not my intention to revisit the history of gene technology or of the *Gene Technology Act* 2000 (Cth) (GTA/the Act) in any great detail. Rather I seek to examine how the public forced open channels of communication with government and the effect of this exchange upon both government policy and the course of regulatory reform.

14.1 INITIAL CONSULTATIONS

In the previous chapter I argued that the Government came lately to the idea of participatory risk governance. This is not to say that the Government dragged its feet entirely. Legislative reform was mooted as early as 1992 with the House Committee arguing that it would be 'prudent' to replace the GMAC regime with a statutory one [see 3.1.2]. Lack of vision and political commitment meant those recommendations fall by the wayside. Had this not happened, we might have experienced a very different political and legal outcome following the commercialisation of gene technology.

On the one hand, it is arguable that the existence of a regulatory regime may have mitigated or minimised the degree of public backlash. This is because the regulatory lacuna existing at the time of commercialisation heightened the perception that the Government was not at arms length from industry. Furthermore, the lack of a risk analysis regime backed by actual enforcement mechanisms provided ammunition for opposition groups to argue that the technology was not being controlled.

On the other hand, had the legislation been passed at this early stage, we might find a very different regime in place. The House adopted a rather narrow view of risk and ethics and placed much less emphasis on risk communication than would be found in later governmental inquiries (particularly that of the Senate [see 14.4.3]). The regime proposed in that report was little different than the non-statutory GMAC system albeit with legislative underpinnings. It appears to have been created with the view that risk assessment and management backed by legislative provisions alone (non-deliberative risk governance) would serve to assuage community concerns. Given the broader risk perception experienced

during the backlash there is cause to question whether such legislation would have been fully effective in creating community trust and support.

The attitude to regulatory reform seems not to have changed five years on, despite the increasing public attention on and dissatisfaction with the oversight of gene technology by 1997. At that time the Standing Committee on Agriculture and Resource Management (SCARM) again argued for the need for comprehensive legislation covering gene technology [see 3.3].

SCARM argued that gene technology was of great benefit to the Australian public. They provided no evidence base to back this claim and there is no indication they actually asked members of the Australian public whether this was the case. What concerned them was the growing controversy surrounding gene technology would undermine the 'great benefits' that would accrue from the commercialisation of gene technology. According to SCARM, the primary cause of the public controversy was 'uncertainty' over the 'ad hoc' regime in place at the time. Again, this appears to be an assumption as there was no direct or indirect consultation with the public to confirm this.

SCARM argued that the only way to remedy public uncertainty was for the Government to legislate in the area. Doing so would 'assure consumers' that risks were being adequately dealt with. There was no suggestion that legislation might empower represent or involve consumers. SCARM also argued that a legislative regime would provide assurance to industry that their products would have a clear path to market – in other words, that the public backlash would not affect them.

Like the 1992 House Committee, SCARM seems to have assumed that by ensuring a strict risk assessment and management regime was in place, most of the public fear over the technology would dissipate. Whilst it is true that the public did indeed express anxiety over the lack of effective technical risk governance, this does not present the entire picture. What became clear later on was that a large percentage of the public (*general, informed, active)* expected a more open, representative and inclusive form of risk governance and one that took into account more than just physical hazards.

The original SCARM regime is another example of the type of management process that develops from a lack of community consultation and how false assumptions lead to incomplete strategies being adopted. The proposed regime would have done little more than legitimise the existing GMAC system. It would have been technically oriented, focused on quantifiable risk assessment as the core decision making tool and have not placed ethical or community concerns at the heart of the decision making process. Yet the SCARM proposal can be seen as the embryo of what later was to become the GTA, a much more complex and deliberation oriented act [see for instance 15.1-15.2,16.2-0,17.2,18.1-18.2]. What caused the transition from a technically driven to participatory regime was a combination of the proxy stage 3 environment that arose during the consultation period, and the nature of the consultation itself.

14.2 INITIATING DIALOGUE : THE CONSULTATION PROCESS

Regulatory reform may have originally been envisioned as a tool to mollify the public, but once the process of reform got underway it took on a life of its own. By moving into the legislative domain gene technology became subject to the rules of statutory *enactment* that are part of the process of drafting [see 12.4], in particular the obligation to consult with affected parties. This provided Parliament and the people the first real chance to debate and consider the technology in a public arena. As will be seen below it was in the process of consultation over the form and scope of the Gene Technology Bill that turned a proxy stage 3 environment into a real stage 3 multidirectional interchange.

In chapter 12 I examined the correlative move in both risk and regulatory practice towards a broader and more process oriented approach to public involvement and communication. Thus, we see a move towards the institutionalisation of consultation in regulatory reform at the commonwealth level [see 12.2-12.4]. By the time of the SCARM report it was mandatory for Commonwealth agencies responsible for the implementation of new legislation to consult with those who might be affected by such reform. In respect of the GTA these consultations were

wide ranging and involved a large number of government, industry, stakeholder and citizen groups.[1]

The consultation process for the GTA is discussed variously through chapter 3 but I will summarise the more important features for clarity's sake. Because of the much higher level of interest in gene technology subsequent to its commercialisation, the Commonwealth State Consultative Group on Gene Technology (CSCG) took almost two years (1997-1998) to complete its consultation on the most appropriate regulatory option for gene technology [see 3.3].[2] Based on this preliminary round of consultations the CSCG drafted a proposed regulatory system underpinned by broad policy principles and sought further broad ranging input in the form of submissions and Australia wide consultations.[3] Based on this feedback a draft Gene Technology Bill was drafted in cooperation with the Interim Office of the Gene Technology Regulator (Interim OGTR) to a further round of submissions and consultations [see 3.11] which the Interim OGTR also cooperated in overseeing. For simplicity's sake I will continue to refer to this process as the CSCG consultation although after August 1999 it effectively became the CSCG/Interim OGTR consultation.

The Australian Centre for Environmental Law criticised the consultation approach adopted by the Commonwealth, stating:

> [t]he Discussion Paper states that the paramount object of the new regulatory system – protection of human health and safety and the environment – will be underpinned by guiding "Policy Principles" ... These principles were apparently unilaterally agreed on, without public input, by the Commonwealth State Consultative Group on

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[1] The situation may have been quite different had the initial 1992 House recommendations for regulatory reform have been adopted. That is because, firstly, it was not a mandatory requirement to consult widely at that stage (although it was general regulatory practice), and secondly there were much fewer stakeholder and public interest groups at that time.

[2] Bodies consulted included: universities; consumer groups; environmental organisations; health professionals; the gene technology industry; retailers; the food industry; and primary producer groups. Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra. p 36.

[3] Commonwealth State Consultative Group on Gene Technology (CSCG) 'Regulation of Gene Technology,' Commonwealth of Australia, AGPS, 1998.

> Gene Technology ... This is yet another failure of public consultation in the realm of GMOs. [4]

The assertion that the policy principles were decided upon 'without public input' seems overstated. They were arrived at subsequent to an initial round of consultation with the public. The fact that policy principles were settled *subsequent to* consultation rather than *directly in consultation with* the public perhaps raises the question of how involved the community must be in the consultation process. As was noted above, there should not be an over-reliance on external data, so that it replaces responsible governance. The drafting process is a technical one and needs to allow experts to translate lay views into the legislative form. To require draftsmen to consult the public at every stage of the process would have created an unwieldily consultation process which would have unreasonably delayed the passage of the Bill. Public involvement in regulatory reform is an integral part of the overall process, but it cannot be allowed to dominate that process so that it becomes unworkable.

The CSCG consultation process was the first real platform for centralised deliberation on gene technology in Australia. It was wide ranging, allowing individuals from across the political and social spectrum to contribute to the development of the GTA. All those with an interest were provided with an opportunity to have their voice heard, not merely those with the power or resources to get their message across. Although different sides of the debate rarely gave evidence at the same time, or came into direct contact with each other they were able to consider and respond to opposing views, in oral and written evidence. Indeed, some groups were forced to explain why their viewpoints differed to others. The result was a multi-directional dialogue, albeit indirect, with the Government providing a centralised nexus point for broad ranging deliberation.

The consultation process therefore became a place in which a debate about the technology and the way it was managed could occur, even though it was ostensibly set up to decide on the best form of legislative replacement for the

[4]Anton D.K., Submission To The Senate Community Affairs References Committee in the matter of the Inquiry into the *Gene Technology Bill* 2000, Australian Centre for Environmental Law, 2000, p 2.

existing regime. It moved the proxy stage 3 dialogue into a real stage 3 process. Moreover it served to stimulate further debate and fortify further community action as potentially affected constituencies began to consider and articulate their response to proposed legislation and its subject matter.

Consultations tend to be both reactive and reflexive, in that they seek to determine the lay of the socio-political landscape but in doing so alter that landscape. This can be seen with the dramatic increase in stakeholder activity in response to the CSCG consultations and through the process of drafting of the Gene Technology Bill [see 3.5-3.6]. At the conclusion of the process the CSCG reported an 'unprecedented' level of participation from across the Australian community. Many hundreds of written submissions were received and hearing times in several states had to be extended to allow all interested parties to participate.

The unprecedented level of participation in regulatory drafting brought home to the Government the degree of concern in the community about gene technology. The process highlighted that: there were more than a 'noisy minority' advocating caution; community concerns were real and varied; and mechanisms for interacting with the public at the decision-making level needed to be drastically improved.[5] The result was a steady shift towards a more holistic view of risk governance as the consultation process progressed. Whereas the Government press release announcing the beginning of the CSCG inquiry concentrated almost exclusively about institutionalising risk analysis (as recommended by SCARM) the one announcing the conclusion of that process placed a much greater emphasis on how the new regime would ensure 'public input into decisions'. The shift in governmental rhetoric evidences how multi-directional communication can render the process of regulating malleable and reactive.

Certainly other factors contributed to the growing realisation within government that risk governance needed to be broader than mere risk assessment (for instance the Consensus Conference and Senate Committee [see below]). However, the consultation process for the GTA must be seen as one of the most influential

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[5] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000. p xi.

events in the move towards deliberative risk governance in Australia. It was influential in the way that it made the Government aware just how important openness and inclusiveness were to the public. It was also influential in the way it made the community focus on regulation as a solution to perceived inadequacies with the oversight of gene technology. Moreover, it proved to that community that the Government was willing to work in collaboration with those affected to remedy the situation and act at arms length from industry.

One of the greatest challenges to the consultation process is to overcome the difficulties of sectional groups dominating and even driving the discussion [see above 12.5]. The dominance of powerful lobby groups at the expense of others can lead to disillusionment in the process and a lack of trust in the implemented legislation.[6] Whilst such a scenario may not have been completely avoided in the design of the GTA, the substantial involvement of a broad spectrum of interests goes a long way to fostering trust in the regime. The Government's ability to adequately balance and manage the process was generally well received by those participating. Whilst some were unhappy with the outcome of the consultations there is little evidence of discord over the process itself or the manner in which the CSCG interacted with people. Indeed many parties, including those opposed to gene technology commended the Government for its consultation process.[7]

14.3 FINDING A COMMUNICATION STOP-GAP

Whilst the consultation process was well received by participants and critics, it was not, of itself, a complete solution to the lack of government led dialogue on gene technology. The consultation process had a singular focus and required participants to address specific questions and criteria. As I stated above, it was

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[6] For instance Hall argues that lobby groups can 'distort public policy' because marginalised and less powerful groups within the Community can struggle to get their issues heard and properly addressed'. Hall K, *Legislation*, Butterworths, Sydney, 2002, p 55. See also, Hartley T.C, Griffith J, *Government and Law* 2nd ed., Weidenfeld and Nicolson, London, 1981 p 211. Beer S.H, *Modern British Politics: A Study of Parties and Pressure Groups*, Faber, London 1965; Mason S 'Law-making, drafting and law reform' in *Essays on L*egislative Drafting, Adelaide Law Review Association, Adelaide, 1988 pp 115-117 ; Rush M, 'Lobbying Parliament'(1990) Parliamentary Affairs **43**:141-8

7 Anthony L, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 30/8/2000, p 19616.

used nonetheless as a sounding board for public concerns generally, but this does not diminish the fact that the process had a specific goal in mind, namely regulatory reform. Moreover, regulatory consultation is generally input oriented. Whilst there is a degree of feedback through reporting such output is limited in scope and detail. It does not provide the mechanism for an iterative, responsive and multi-directional interchange. Nor is the process set up to ensure that all participants are raised to the same knowledge benchmark through the provision of tailored information.

Most importantly regulatory consultation had not satisfied the public demand for government led dialogue on gene technology. Indeed, quite the opposite was true; the process had served to whet the public's appetite for a more complete dialogue. It had also helped forge and motivate interest groups who were now lobbying for the Government to ensure such dialogue occurred. However, until the GTA came into effect there were simply no institutional mechanisms through which the Government could respond to the demand for wide-scale deliberation and debate. In the absence of a body or regulatory structure ancillary policy approaches were turned to. These were the Consensus Conference and Biotechnology Australia.

14.3.1 CONSENSUS CONFERENCE

The *First Australian Consensus Conference on Gene Technology in the Food Chain* (the Consensus Conference) took place in 1999 between the initial round of CSCG regulatory consultations [see above] and the Parliamentary inquiries [see below]. The structure and purpose of this conference was discussed previously [see 3.6]. This conference was not originally a government led initiative. Instead, it was organised by the Australian Consumers Association and convened by the Australian National Museum.[8] Nevertheless the Conference remains relevant to the current discussion because of the financial and logistical support given to it by all levels of government[9] and the fact that the Lay Panel's findings were subsumed into the drafting process. [10]

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[8] Mohr A, 'Of Being Seen to do the Right Thing ...' (2002) *Science and Public Policy*, 1:**29**::12.

[9] Sponsors included; Agriculture Western Australia; Australian Consumers Association; AVCARE; AWRAP - Australian Wool Research and Promotion Organisation; CLIMA - Centre for Legumes in Mediterranean

As a result of the conference the Interim OGTR, released an information bulletin entitled *How Outcomes Of The First Consensus Conference On Gene Technology In The Food Chain Are Being Addressed*.[11] That bulletin noted:

> [w]e are using the Lay Panel's report as one of the guides to the development of the new regulatory system – we have tried to interpret the spirit and intention of the Lay Panel's recommendations, and apply them not only to the specific issues raised by the Panel, but also more broadly to matters dealt with in the national regulatory system.[12]

The bulletin responded to each of the Lay Panel's main recommendations and in some instances altered the form of the proposed regulation as a result, particularly the form of the Gene Technology Community Consultative Committee (the Community Committee) [see 15.2]).

The original Gene Technology Bill contained no community committee. Rather it was expected that the Gene Technology Technical Advisory Committee (the Technical Committee), would give representation to lay and stakeholder interests. This system was considered to be unsatisfactory by the Lay Panel of the

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Agriculture, University of WA; Cotton Research and Development Corporation; CSIRO; CSIRO - Cooperative Research Centre for Vertebrate Biocontrol; Dairy Research and Development Corporation; Department of Primary Industries & Fisheries NT; Department of Agriculture Fisheries and Forestry – Australia; Dried Fruit Research and Development Corporation; Environment Australia; Fisheries Research and Development Corporation; Forest and Wood Products Research and Development Corporation; Grains Research and Development Corporation; Grape and Wine Research and Development Corporation; Horticulture Research and Development Corporation; Land and Water Research and Development Corporation; Marsupial CRC; Meat Research Corporation; The Myer Foundation; Natural Resources and Environment VIC; Pig Research and Development Corporation; Rural Industries Research and Development Corporation; South Australian Research and Development Institute; Sugar Research and Development Corporation; Tobacco Research and Development Corporation.

See the Consensus Website, <http://www.austmus.gov.au/consensus/05.htm> (6/1/03).

[10] It is interesting to note that the Conference is still seen as relevant to the ongoing operation of the OGTR and the Lay Panel Report is reproduced in full on the OGTR's website. See,

<http://www.ogtr.gov.au/volsys/bulletin4index.htm> (13/1/03).

[11] Interim Office of the Gene Technology Regulator *How outcomes of the First Concensus Conference on Gene Technology in the Food Chain are Being Addressed. Information Bulletin No.4*, Commonwealth of Australia (AGPS), Canberra, 2000. ,

[12] *ibid.* p 27.

Consensus Conference [see 3.6]. It called for broader community and stakeholder participation and representation, recommending that:

> Government should embrace a commitment to bring together all stakeholders to talk to each other to reach agreement on mutually beneficial solutions. In short, government, in conjunction with the proposed Gene Technology Office as described above, should act as a facilitator rather than an arbitrator.
>
> Government should establish mechanisms similar to the model of the Consensus Conference, to bring together industry, consumer groups, critics, other experts and Australian lay people. This would ensure that dialogue between all of these groups would lead to better government decisions. [13]

In response to these comments, the Interim OGTR created a third advisory body within the Gene Technology Bill [additional to the Technical Committee and the Ethics Committee, see 4.4], entitled the Gene Technology Community Consultative Group.[14] It was envisioned that this consultative group would generate discussion on general issues to 'inform policy development and regulation'.[15] The group was to consider 'matters of general concern' at the behest of the Regulator or Ministerial Council.[16]

Of further note is the response of the Interim OGTR to the Lay Panel's criticism of the GMAC system:

> [f]or this new system of regulation to work, we must ensure that … Any person in Australia must be able to access information about the regulatory system and the products it controls, and have the

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[13] *First Australian Consensus Conference Gene Technology In The Food Chain*, Lay Panel Report, The Australian Museum, Canberra, 1999, <http://www.austmus.gov.au/pdf/layreport.pdf> (10/10/02), p 6.

[14] Interim Office of the Gene Technology Regulator, *How Outcomes Of The First Concensus Conference On Gene Technology In The Food Chain Are Being Addressed*, Information Bulletin 4, Commonwealth of Australia (AGPS), Canberra, 2000, p 10.

[15] *ibid.*

[16] Interim Office of the Gene Technology Regulator, *Quarterly Report* (June 2000), Commonwealth of Australia (AGPS), Canberra, 2000, p 41.

> opportunity to be involved in decisions about what activities should be permitted in Australia …
>
> The new legislation makes sure there is open and easy access to information. It also sets out a process so that any interested person can be involved in decision-making.[17]

The Interim OGTR went on to outline the mechanisms by which it would ensure such a system. These included requirements to:

- involve the public in risk assessment and management;
- report on how the public was being involved;
- provide accessible information of GMOs and GM products; and
- report to Parliament and consult with the community on the development of 'key documents that guide regulatory decisions'.

Thus, the response of the Interim OGTR (and hence Government) to the Lay Panel report constitutes at the least a promise to institute a deliberative risk governance regime. Further to the Interim OGTR bulletin, the Lay Panel report was to feature extensively in Parliamentary debates and inquiries [see 14.4].[18]

The Consensus Conference marks a confluence between public and governmental dialogue on gene technology and its regulation. This was a privately led initiative that tapped into the public debate and made it outcome oriented by providing the community with an opportunity to input into regulatory reform in an alternative and less formalised manner to the CSCG process. Through it we see the growing influence of the proxy stage 3 environment on the Government and how interest and citizens groups were able to force the Governments hand with respect to public deliberation.

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[17] *ibid*, p 6.

[18] Stott-Despoja N, 'Genetically Modified Food Gene Technology: Human Cloning', *Senate Hansard*, 22/3/1999, p 2965; Bailey F, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19548; Despoja N, '*Gene Technology Bill* 2000 …' *Senate Hansard*, 1/12/2000, p 20460; Tambling G, '*Gene Technology Bill* 2000 … In Committee', *Senate Hansard*, 7/12/2000, p 21220.

14.3.2 BIOTECHNOLOGY AUSTRALIA

It would be disingenuous to suggest the Government did not play a large role in the success of the Consensus Conference, both in terms of the support it provided to it and its willingness to take on board the recommendations of the Lay Panel. Such support was however, after the fact, inasmuch as the conference was a private initiative. In fact, it made the lack of government led deliberation more apparent. Thus, the Commonwealth admitted that:

> [t]here is a strong preference from the community for the Government to be the primary source of information on gene technology. In order that there is public confidence … it is essential that the community continue to contribute to the development of Government policy.[19]

Of course, the realisation of the GTA was still a way off. Indeed the various hurdles that had to be overcome may have meant that the Act would not be enacted or would be limited in scope and jurisdiction. Yet the growing crescendo in the community created a sense of urgency that the legislative process could not meet. Furthermore regulatory consultation provided a multidirectional interchange about risk governance but was limited in its capacity to foster dialogue on the subject of legislative reform – namely technological risk. As previously noted [see 3.14], the Government's solution was to create a non-statutory body (in the same vein as the GMAC), Biotechnology Australia,[20] as part of its Biotechnology Strategy. Establishing a second non-statutory body under the Government's health portfolio allowed the Government to bypass the legislative process and react to the public calls for government-sponsored dialogue on gene technology. It provided the Government with an ancillary stop-gap solution to the lack of government led public dialogues on gene technology.

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[19] Commonwealth Biotechnology Ministerial Council, *National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 1999, p 19.

[20] Whilst there are several other Commonwealth bodies apart from the GMAC and the Interim OGTR, which dealt with, and continue to deal with, gene technology, it is Biotechnology Australia which is most relevant to this discussion. Biotechnology Australia is a government appointed body with a core mandate to communicate with the public on gene technology and risk related issues. It has continued this role subsequent to the enactment of the GTA, and some aspects of risk communication may be offset to this body by the OGTR.

Furthermore its creation is evidence of the recognition by the Government that effective risk communication is a precursor to public acceptance of novel technology. That said, Biotechnology Australia is, in very many ways, a transitional organisation.

Obviously, Biotechnology Australia is transitional in the sense that it provided a stopgap solution between the stage 1 GMAC and the stage 4 Office of the Gene Technology Regulator (OGTR). As a non-regulatory agency, it could never gain complete institutional legitimacy – and thereby a stage 4 status. However, it could also be seen as transitional insofar as it revealed a governmental mindset that was still somewhat reluctant to fully engage with the public. The principal concern raised by critics is the overlapping roles set out for the organization under the Biotechnology Strategy. Public awareness is only one aspect of its mandate; the remainder is dedicated to support and development of gene technology and the Australian gene technology industry [see 3.14]. Indeed, the majority of the organisation's resources and infrastructure are dedicated to the promotion of the technology generally.[21]

From its inception it was near impossible for the public awareness arm of Biotechnology Australia to separate itself out from these other pro-industry arms.[22] By association, its messages become mixed with those of industry. The result is an appearance of corporate and governmental collusion. The Democrats argued that it was:

> somewhat unfortunate [that] Biotechnology Australia –which was set up by the Government for an educative role – as with other people who are quite close to the technology, becomes very enthusiastic to the point of becoming promoters rather than debaters of the pros and cons of the issue and, at times, it is very hard to pick the authority who is speaking to the group or writing the article that one is reading to

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[21] Commonwealth Biotechnology Ministerial Council, *National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 1999.

[22] "[s]ome may view the interface between science and government as being as problematic as insufficient public education about genetic engineering issues in the past, weakness in the interface contributing to a less than adequate public communications process." Polya R, *Genetically Modified Foods - Are We Worried Yet?*, Australian Parliamentary Library, Science Technology, Environment and Resources Group Current Issues Brief No.23, 1999, p 2.

> determine their total detachment from having a personal bias in this issue.[23]

Whilst in practice Biotechnology Australia maintains 'chinese-walls' between its various arms, [24](in particular the industry development and public education sections) it is easy to see how it may not be seen as a totally impartial and independent agency. Such perceptions are compounded by the way that the organisation was promoted in other arenas. For instance, in describing the role of Biotechnology Australia, the Minister informed the House it would be 'responsible for working with all the stakeholders in this industry to develop that national strategy and manage the Government's biotechnology approach.'[25] Note that the relevant stakeholders were industry alone and not citizen, consumer, environmental or other interest groups. Instead of 'working' with these non-industry groups, Biotechnology Australia's role is to 'provide them with information'.[26]

Suggested methods of 'educating' the public set out in the National Biotechnology Strategy include consumer research, brochure distribution, information forums, education kits for schools and free-call hotlines.[27] Whilst laudable, these processes are largely unidirectional and could easily be mistaken for a public relations campaign. Indeed, the Australian Consumers' Association referred to Biotechnology Australia's information leaflets as a 'sales brochure for

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[23] Gilfillan I 'Genetically Modified Material (Temporary Prohibition) Bill,' *Legislative Council Hansard (South Australia)*, 4/4/2001, p 1243.

[24] In response to questions about Biotechnology Australia's allegiances the Public Awareness Manager wrote 'Biotechnology Australia does not currently contract any commercial PR firms to provide any strategy input, and does not seek to promote the industry (although there is often confusion over this since there is a separate industry development part of Biotechnology Australia - who we are unable to work too closely with)' see *[Biomedia] Review comments on Sunderland Paper :*
<http://listserv.cddc.vt.edu/pipermail/biomedia/20020711/000045.html> (10/10/02).

[25] Minchin N, 'Question without Notice: Biotechnology' *Senate Hansard*, 24/5/1999 ,p 5152.

[26] See The Biotechnology of Australia Website at: http://www.biotechnology.gov.au/ (8/8/02).

[27] Commonwealth Biotechnology Ministerial Council, *National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 1999, page 11. also House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* Report (February 1992), Commonwealth of Australia(AGPS), Canberra, paras 3.28- 3.32.

GM foods'.[28] Such criticisms are unavoidable when the strategy outlining Biotechnology Australia uses terms such as 'educating' rather than 'participating' and 'raising awareness' rather than 'listening to'. Dietrich and Schibeci described Biotechnology Australia's communication role as being premised upon a '*lack of [public] awareness* rather than *participation*' with the public:[29]

> [p]articipants in recent workshops were directed to ask; *how well has the National Biotechnology Strategy dealt with education and public awareness?* Not we note, how is public participation being delivered and what contribution is it making? Still the same ignorant public then.[30]

Biotechnology Australia does reflect a movement forward and a realisation that government led dialogue on technology and risk was necessary, but it also indicates that the Government had not fully embraced the idea of egalitarian multi directional dialogue. It marks a reaction to public calls for government led deliberation but not a complete commitment to it. As one author notes:

> [c]ommunication about [gene technology] is more than a marketing exercise – at stake are complex issues of society, culture and science. "Education" will be seen for what it is, a one way authoritarian attempt to manipulate opinion. Communication needs to be aimed at providing the information consumers need, so they can make up their own minds. The difference is subtle but critical.[31]

That the public can 'see through' unidirectional education was proven during the war on error. It also became apparent with the mixed reception to Biotechnology Australia by the public. Various stakeholders, public interest groups, academics

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[28] Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill*, Commonwealth of Australia(AGPS), Canberra, 2000, par 3.189.

[29] Dietrich & Schibeci *op cit*, 4 p 16.

[30] *ibid.*

[31] Bezar H, *Genetic Modification/Communication Strategie*s, Crop & Food Research Report, Genetic Modifications Summit, NZ, 2002 <http://www.conferenz.co.nz/library/paper_list.htm> (11/8/02).

and politicians have castigated the body over its structure and role.[32] The Opposition described Biotechnology Australia as a part of an overall 'public relations disaster', having only limited success in communicating gene technology to the public, despite its considerable budget.[33] They argued that it failed in its task because the public was suspicious of its motives given its inability to place itself 'at arms length from the industry'.[34]

I noted above that, as a non-statutory authority, Biotechnology Australia would never gain true institutional legitimacy. I argued that this was acceptable given that it allowed the Government to provide some form of public body capable of leading a public dialogue on gene technology (whether or not this actually eventuated in practice). The down side was that, despite reflecting a rather transitional view of risk communication, Biotechnology Australia was set up as a permanent body and its communication role continued on after the establishment of the OGTR.

The National Biotechnology Strategy charged it to work alongside the OGTR to oversee 'non-regulatory biotechnology issues' including the provision of information on gene technology to the public. This effectively means that part of the role of communicating about gene technology's risks remains with the policy based Biotechnology Australia rather than the regulatory OGTR. This split vision of risk communication drew criticism from all sectors, including from within the Government itself. The Honourable Fran Bailey (Government) who chaired the House Committee Inquiry into gene technology argued:

> [t]here is no doubt that the community has suffered from lack of factual information and it is vital that they receive it. For this reason, I

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[32] Anon., 'Modified Attitudes' (2003) *New Scientist*. 2409:**179**:45 ; Gilfillan I Genetically Modified Material (Temporary Prohibition) Bill, *Legislative Council Hansard (South Australia)*, 4/4/2001, p 1243 ; Dietrich, H.& Schibeci, R. 'Beyond public perceptions of gene technology: community participation public policy in Australia.' Paper Presented at, *Towards Humane Technologies Conference* (15-17 July, 2002) , University of Queensland, 2002; Anna Salleh A, Fry R, *Gene technology agencies stand by survey conclusions*, ABC Science Online,
<http://www.abc.net.au/science/news/health/HealthRepublish_446198.htm> (4/7/03).

[33] Sidebottom S, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19536.

[34] *ibid.*

> state again on the public record, … how important it is that Biotechnology Australia be made a statutory authority. If [it] is to be a credible source of information, it must not only be seen to be independent but be independent. By being a statutory authority, it would be at arms-length from ministerial control while still accountable to parliament and subject to audit by the Auditor-General.[35]

Opposition members also argued that:

> Biotechnology Australia [should] become a statutory authority … to keep it at arms length from the industry, where it was seen, as part of its charter, to be promoting biotechnology and, some would argue, in particular GMOs.[36]

The lack of proper institutional underpinnings leaves the organisation at best capable of reaching a stage 3 status. Furthermore, the way the organisation approaches communication seems to indicate it is really a stage 2 organisation because it appears agenda driven and to really be promoting the technology rather than promoting dialogue about it. Whilst its public education arm may strive to ensure it remains impartial, it will always be under the shadow of its industry development arm. The effect of this policy standpoint on the ongoing operation of the GTA will be considered in following chapters [see 15.2, 0, 17.2.4].

14.4 PARLIAMENTARY INQUIRIES

There were mixed messages from the Government in the lead up to the enactment of the GTA. On the one hand: the CSCG consultation; the support given to the Consensus Conference; and the willingness to include the Lay Panel's recommendations into the drafting process evince an increased recognition of the importance public input and involvement in risk governance. Furthermore,

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[35] Bailey F, '*Gene Technology Bill* … Second Reading', 29/8/2000, House Hansard, p19548.

[36] Sidebottom S, 'Committees: Primary Industries and Regional Services Committee: Report', *House Hansard*,: 2/11/2000 p: 22079.

vesting Biotechnology Australia with a public engagement role indicates the acceptance that the Government needed to take the lead in communicating about gene technology and its risks. On the other hand the structure and mandate of Biotechnology Australia reveals an uneasy tension between the Government's objectives of promoting the technology and promoting its own risk communication policy (particularly the NHP Guidelines [see 12.2]). There is evidence of a residual perception in government circles that completely involving the public over the long term might be disadvantageous to the commercialisation of the technology.

The tension between promoting industry and committing to complete involvement was particularly evident in the final stage of drafting of the Gene Technology Bill wherein both houses of parliament undertook separate legislative inquiries.[37] These inquiries are particularly important, not only because they represent a major undertaking in terms of multi-directional regulatory communication, but also because they provide a fascinating example of how input and pressure from differing constituencies can influence the course of regulatory reform.

The House inquiry was undertaken by the *Standing Committee on Primary Industries and Regional Services* [see 3.7]. It was charged with considering, *inter alia*, 'opportunities to educate the community of the *benefits* of gene technology [emphasis added]'. The *Community Affairs Reference Committee* oversaw the Senate inquiry [see 3.13]. The main terms of reference of the Senate Committee were to investigate whether the measures in the Gene Technology Bill were adequate and achieved the desired object of the proposed regime and secondly whether the proposed regulatory arrangements and public reporting provisions would provide sufficient consumer confidence in the regulation of gene technology.[38]

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[37] Note that the House inquiry was not specifically charged with examining the Bill, but a variety of considerations with relation to promoting the technology in Australia. However, it ostensibly considered the Bill in respect of all its terms of reference.

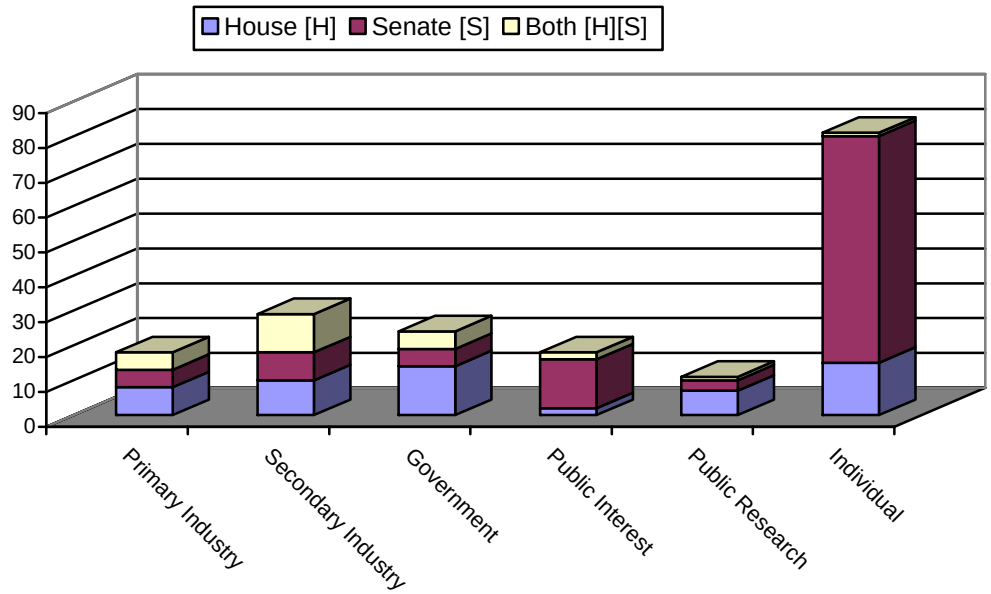
[38] Senate Community Affairs References Committee, *A Cautionary Tale: A Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill*, Commonwealth of Australia(AGPS), Canberra, 2000, para 1.2.

In all 200 written submissions were received during by these two inquiries along with oral opinion from speakers and attendants drawn from various stakeholder and community groups. These submissions are important because they provided stakeholders and sectional interests an opportunity to provide a formal and considered comment on the final draft of the bill before it entered each house of Parliament. They also provided an avenue for citizens to communicate directly with the actual legislative body (Parliament) rather than to just the drafting bodies (CSCG, Interim OGTR). Submissions were backed up by face-to-face consultations in which participants could explain their positions, concerns and ideas with those about to enter debates on the Bill.

14.4.1 REFERENCE, REPRESENTATION AND RHETORIC

The agendas of each committee affected the type of bodies that were called to give evidence or whom volunteered submissions. As can be seen from Figure 6 the House inquiry received a greater proportion of submissions from primary and secondary industry (producer and manufacturer stakeholders), government and public research bodies. Conversely the Senate received a greater proportion of submissions from citizen groups (environmental, consumer stakeholders etc.) and members of the public (individual submissions).

Figure 6 (RESPONSE TO HOUSE AND SENATE INQUIRIES)[39]



[39] Information sourced from Appendix 3.

The most involved group was industry, particularly if primary and secondary industries are taken together. Secondary industry (gene technology, seed and food distribution/supply companies) had the highest percentage of group representation at both inquiries, followed by primary industry and various industry departments of government. Individuals had the lowest percentage of cross-inquiry representation followed by public research institutions and public interest institutions.

In addition, industry was able to create a strong presence early on – not least because it was the *Primary Industry & Regional Services Committee* that was charged with undertaking the inquiry. There was a significant advantage to industry in having its say early in the piece because the initial inquiry was used extensively in the House debates.[40] Subsequent House speeches tended, in general, to be more industry focused, relating directly or incidentally to the impact of the technology or regulation on industry.[41] Major concerns included how to ensure that farmers and local gene technology companies benefited from the technology, how the organics industry would be protected, or the effect of consumer concerns on the continued development of the technology.[42]

The opinions of private individuals and public interest organisations would only fully feature later in the debate – after the House had completed its deliberation on, alteration and approval of the Bill. As a result senate debate tended to focus more on ethics, consumer concerns and the environment.[43]

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[40] Jenkins H, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 28/7/2000, p 19473 ; Arden P, 'Gene Technology: Environment', *House Hansard*, 21/6/2000, p 17925 ; Secker M, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19540 ; Murphy J, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/ 2000, p 19544; Bailey F, *Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19548; Andren, P , '*Gene Technology Bill* 2000 Cognate Bills: Gene Technology (Licence Charges) Bill 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19562; Hall J, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19567 ; Lawrence C, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 29/8/2000, p 19579

[41] See *House Hansard* 28/8/2000-30/8/2000, pp 19449 - 19479, 19533- 19583; 19616-19617.

[42] *ibid.*

[43] Thus the major amendments or proposed amendment made by the Senate were, the inclusion of a precautionary principle, the strengthening of the community and ethics committees, the proposal to make the

14.4.2 THE HOUSE COMMITTEE: BEYOND ITS TERMS OF REFERENCE

As noted above, the position of the House Committee was, in a way, reflective of the transitional attitude of the Government towards the technology, stakeholders and industry. Charging the Primary Industry and Regional Services Committee with undertaking the inquiry was perhaps the most obvious example of tipping the balance in favour of industry. However, it was perhaps the terms of reference that demonstrated the reluctance on behalf of Government to involve the public on an equal footing with industry. Whilst the reference did refer to the public, it was in terms of *educating* them to the benefits of gene technology not *informing* them community about the technology so that they could make up their own minds.

Despite the limitations of its original mandate, it must be recognized that the House Committee spent a great deal of time examining the need to involve the public in a real and participatory manner. The committee argued that:

> [t]here are benefits and risks associated with gene technology, and there is a need to provide balanced information about them in an open and credible manner. Particular emphasis needs to be placed on addressing consumer concerns associated with risk, and how these risks are dealt with in the regulatory framework.[44]

The fact the Committee spent so much time considering public interest concerns is perhaps a signal of the weight of public opinion at the time. What is extremely interesting is that, within the entire chapter of the House Report dedicated to risk communication, no public interest, citizen or consumer organisation submissions

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OGTR a statutory office of three persons rather than one (so as to minimise the chance of 'capture'), the prohibition of cloning, the addition of more regular and involved reporting requirements and more stringent provisions for enforcement, licensing and monitoring. See: Eggleston A, 'Gene Technology (Consequential Amendments) Bill 2000 Gene Technology (Licence Charges) Bill 2000: Second Reading', Senate Hansard, 7/11/2000p 19302: Forshaw M, '*Gene Technology Bill* 2000 … Second Reading', Date: 6/11/2000, *Senate Hansard* , p 19192; Stott-Despoja, N '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 7/11/2000, p 19291; Brown B, 'Gene Technology (Consequential Amendments) Bill 2000 Gene Technology (Licence Charges) Bill 2000: Second Reading', 7/ 11/2000, Senate Hansard, p 19307.

[44] *ibid.* para 3.2.

are noted.[45] This is perhaps surprising given that informing the public would seem a central issue for such bodies.[46] Instead it was industry (and to a lesser extent research organisations) that encouraged the Government to engage with the public. The House Committee states within that chapter:

> Lack of consumer confidence in gene technology and the government authorities responsible for its regulation have generated public feelings of distrust and suspicion.[47]
>
> Citing calls from the industry and Government the Committee notes that :
>
> Effective consumer participation in decision-making is only possible if good information is available to all involved. Information is also crucial to consultative processes such as those established to develop the new legislation, and to provide input to the Regulator's decisions.[48]

Some industry and research groups went so far as to call for an integrative model arguing that consumers should be 'listened to' and that 'it is critical to involve all stakeholders and engage [in] an informed and public debate seeking to resolve issues rather than just creating conflict and polarisation'.[49] The Committee concluded that:

> to be fully effective, an information campaign should acknowledge the value that consumers place on environmental, economic, ethical and social considerations, and address them.[50]

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[45] *ibid.* Chapter 3.

[46] Note, the one non industry source relied upon is the Consensus Committee. However this group did not present a submission or participate in the Inquiry. Rather the Lay Panel report was utilised as a reference point for community concerns.

[47] House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* Report (February 1992), Commonwealth of Australia(AGPS), Canberra. para 3.5.

[48] *ibid,* para 3.7.

[49] *ibid,* para 3.25.

[50] *ibid,* Paras, 3.21 & 3.45.

Certainly, the House Report cannot be said to advance a system that places the community *on par* with industry. It views risk communication as a 'strategy', and tends not to follow the line of 'involving all stakeholders' in the actual decision making process, as was recommended by some industry and government groups. The Report focuses on the 'provision' of information rather than the *exchange* of information. It also assumes that the public will eventually acquiesce to the technology should they receive the 'right' information. Nevertheless, the report is evidence of an attitudinal shift by both industry and the Government towards, at the very least, creating the appearance of a more inclusive form of risk communication.

14.4.3 THE SENATE COMMITTEE: REBALANCING REPRESENTATION

The Senate inquiry was, in part, called for by the Opposition and minor parties, to balance the early over representation of industry interests in previous government consultations (particularly the House inquiry). [51] The initial response by the Government, was to describe calls for a Senate inquiry as a 'delaying tactic' intended to put off the implementation of the legislation.[52] They further argued that if such an inquiry were to go ahead a legislative committee and not a community consultation committee should undertake it.[53] The Senate, however, rejected this argument and decided to pursue the inquiry as:

> even after the public consultation on the draft bill issued by the Government, there were many concerns about the provisions in the draft bill raised both by the community generally and by many of the major stakeholders. We believed that it was important that the community, industry, science organisations and environmental organisations be given an opportunity to speak to the parliamentary committee to air their concerns.[54]

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[51] Forshaw M, '*Gene Technology Bill* 2000 … Second Reading', 6/11/2000, *Senate Hansard*, p: 19192, Bartlett A, 'Committees: Community Affairs Legislation Committee', 2/11/2000, *Senate Hansard*, p 19024.

[52] Knowles S, '*Gene Technology Bill* 2000: Report Of Community Affairs References Committee date: 1 November 2000', *Senate Hansard*, 1/11/2000, p 18857.

[53] *ibid.*

[54] Forshaw M '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard*, 6/11/ 2000, p 19192.

The introduction of this committee ensured that, overall, there was a relatively even spread of community representation [illustrated in Figure 6]. The high number of individual and public interest submissions to this inquiry evince a willingness of community members to participate in a formal process of consultation and deliberation. As the Senate Committee noted:

> [a] broad range of interested individuals and organisations and the community generally expressed their concerns and fears about aspects of the Bill, and in particular, the adequacy of the proposed regulatory framework to address these concerns.
>
> There were a number of features to emerge from our inquiry. One of the most important was the significant number of and qualifications of scientists opposed to, or very concerned about, gene technology, its applications and possible consequences. Protagonists of gene technology who described opponents as 'a noisy minority' or 'extremists' did not reflect the breadth of concern in the community or the weight of serious and scientific opposition. And they did little to persuade people to their point of view with such derogatory language.[55]

The Senate report was not at all anti-industry, but it definitely can be seen to be pro-community. For instance, the Senate recommended more stringent reporting and review provisions,[56] as well as arguing for the OGTR to be a statutory authority so as to mitigate bias. [57] It also argued for state opt out clauses and the requirement to inform neighbours of licence conditions [see 17.3]. More importantly it advocated strengthening and formalising the role of the Community Committee, which would later be accepted by the Government [see 15.2].[58] Yet

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[55] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes,* Commonwealth of Australia (AGPS), Canberra, 2000, p xi.

[56] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes,* Commonwealth of Australia (AGPS), Canberra, 2000, paras, 3.165-3.166, 3.222.

[57] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes. A Report On The Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, 2000 para 4.20.

[58] *ibid.*

despite adopting a more community oriented perspective than the House the overall recommendations of these committees are surprisingly similar, particularly in terms of risk governance.

Both committees recommended that gene technology be approached with caution. Furthermore, they both argued that the Bill was a necessary and important piece of legislation. Both recommended the need for the system established by the Bill to be open, transparent and accountable. However, the reasoning behind these recommendations was somewhat different. The Senate tended to assert the need for such principles so as to ensure that the public interest was served and that the public was assured that the concerns they had about gene technology were properly recognised and dealt with.[59] The House generally recommended such principles as crucial devices to assuage public concerns, expressing the view that community support was vital to ensure the continued development of the technology in this country.[60]

The presence of the same core principles within both reports evinces the effect of the proxy stage 3 environment at the time these committees were undertaken. Whilst these principles were being filtered through different messengers, who brought their own interpretive bias to them, it is clear that the social movement surrounding the technology had thrown up some obvious and undeniable facts that

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[59]The Preface of the Senate Report states, "Australia needs an effective regulatory system that is open, transparent and accountable. The consequences of 'getting it wrong' are too grave to contemplate, especially in the longer term. The proposed regulatory regime needs to ensure that there is widespread community confidence in the system. Australia's regulatory system should represent international best practice. Overall, the Committee found that the Bill to introduce regulation into the gene technology area is overdue and very welcome. However, the weight of evidence supported a great deal of caution." Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000, p vii.

[60] The Committee opens the report by stating that, ' Consumer and environmental concerns in several countries are slowing the rate of uptake of GM crops and may even stop it in some cases … Australian primary producers have access to far fewer GM crop varieties, giving rise to fears that Australia's competitiveness in world markets will suffer." *ibid.* paras 1.5-1.6. Chapter 3 of the report is dedicated to examining "consumer attitudes to genetic manipulation which influence the market for GMOs and affect producer readiness to replace conventional varieties with their GM counterparts. This chapter also examines the ways in which public understanding of the issues surrounding the use of GMOs can be enhanced.", *ibid*, para 1.12,

could not be ignored by anyone, including the industry. Principally there was a demand in the community for proper and effective risk governance that incorporated risk communication and deliberation as a fundamental component of the regime. Hence, we see an industry which only a few years before had been telling the community 'trust us its safe' arguing that the Government should involve the public in the decision making process.

14.5 CONCLUSION

At the outset of this thesis I set out to determine whether the GTA was a good law by examining whether it 'achieves its desired purpose'. Yet 'a law' doesn't always have 'a purpose', rather it may have several purposes, stated and unsated, express and implied. Equally the desired purpose of legislative reform may be broader than those stated by those responsible for its inception or implementation. It should also be determined in reference to community expectations for the legislation at the time of its drafting. Examining the dialogue behind the GTA reveals that the community expected openness, transparency, accountability and deliberation; the consideration of ethical and community risks; and most importantly effective risk communication and public deliberation as much as they expected 'scientifically sound risk assessment'.

The gulf between what those initiating regulatory reform saw as its desired purpose and what the community later expressed as their expectations of such reform exemplifies the importance of multidirectional iterative communication to risk governance. It seems that it was the process of regulatory consultation that served to really emphasise the importance of government led dialogue on the risks of the technology proper. Hence, there is a marked shift away from risk assessment towards risk management and communication as the drafting process progressed. There is also a marked development in the roles of the ethics and community committees towards the end of consultations as well as an increasing emphasis on risk communication practice near the end of the drafting process.

Had the community not been consulted prior to legislative *enactment* (i.e. the *making* of law) the Act may very well have taken on a form reflective of

technocratic values rather than community ones. It is questionable whether such legislation would have received community support, increased trust in the Government or been a 'good law', especially from the community's point of view. Consider the different approaches to the development of the GTA versus Biotechnology Australia and the resulting reception to those organizations by the public. Both were developed at around the same time, both by the same government. However the Biotechnology Strategy was not subject to the public consultation, review and input that its regulatory cousin was. Subsequently there is no transition from technocratic values to community ones within that strategy and it expresses a much narrower view of risk communication and indeed the public's capacity to understand risk. Equally, the lack of public involvement in the development of the Biotechnology Strategy has created opposition to it and suspicion of its motives. This is not the case with the development of the GTA. As the current Regulator argues:

> [t]he process of consultation for the Gene Technology was probably one of the most highly consultative regulatory processes that there has been … [the Act] was not something that was just developed in a closed room in Canberra [it] was developed nationally in cooperation with … all the key stakeholders as well as the general public.[61]

There was a commendable effort on the part of those drafting the Gene Technology Bill to reach as wide as possible an audience. This included both the lay public and key stakeholders from groups holding various views on the use and regulation of gene technology. There was also a visible willingness within the Government to allow input through other routes, such as the Consensus Conference. These, combined with the Senate Report, provided a well-rounded consultation process that ensured that the plurality of interests and concerns about the technology were considered and taken into account in the creation of the legislation. The very process served to address one of the desired purposes for legislative reform – at least from the community's point of view. It provided a visible indication that the Government was as willing to listen to the community as it was to industry and that it would take both public and business interests into

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[61] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

account in the creation of the legislation. The long and complex discussion between legislative drafters and the community allowed the Bill to be moulded to capacitate the variety of concerns and perceived risks, which may not have been identified otherwise.

Whilst in combination the various input mechanisms that formed part of the GTA drafting process did ensure a balanced representation of the diversity of community interests there must be a pragmatic realisation that the Government may not have always sought that broad ranging input voluntarily. The House inquiry and the approach taken by the National Biotechnology Strategy indicate that there is some reluctance to raise all parties to the same level and that others may be left out of the process altogether. The reasons for such imbalances are varied: political agendas; private loyalties; or a lack of resources can all contribute to partiality on the part of those managing the communication or consultation process. Indeed a lack of consultation could derive from mere oversight or naivety about the importance of the communication process, as can be seen in the original SCARM report. Tipping the balance back towards broader and more equal representation was the result of pressure from various bodies, both external to and part of Government. Hence the Consensus Conference and Senate Committee became part of the drafting process despite no initial intent by the Government for that to occur.

As the ‘ongoing dialogue’ on the risks of gene technology moves into a legal, post implementation system, it is inappropriate to rely upon the political process alone to impose balanced representation. Whilst public interest in gene technology is still strong, the level of focus and scrutiny levied upon the technology at the time of drafting cannot be sustained, because Parliament’s role is to legislate on all matters. Balance cannot be maintained merely by political means, unless of course the drafting process is re-instigated. Rather it is the law that must now achieve this aim. This is why there was such an emphasis on the need for institutional mechanisms to be introduced into the Act that might impel representative deliberation.

Despite the move to process legitimacy, there is still reason to question whether the processes promised as part of the GTA will be genuinely participatory in practice. The policy of viewing some aspects of risk communication, as a 'non-regulatory' issue – as is the case with the National Biotechnology Strategy – seems to indicate that, whilst there was recognition of the need for immediate intervention, such an involved, wide ranging and in depth level of consultation was perceived to be sustainable over the long term. Thus, a proportion of risk communication was moved outside of the regulatory construct and vested with a policy organisation.

One must recognise the institutional limitation of a regulatory office such as the OGTR to undertake wide scale risk communication that extends beyond its role as a regulatory agency or which does not relate to licence applications. Hence there is an argument for the retention of the role of Biotechnology Australia – although some might argue the way it approaches this role may need re-evaluation. The question will be how this organisation works alongside the OGTR, whether their roles conflict and whether the OGTR can maintain a political distance from the type of communication that has attracted criticism. As will be seen in succeeding chapters the uneasy overlap between the roles of Biotechnology Australia and the OGTR has developed as quite a theme with respect to risk communication about gene technology in Australia.

15

THE GENE TECHNOLOGY ACT AND DELIBERATIVE RISK GOVERNANCE

The previous three chapters have examined first the development of deliberative risk governance and secondly how that process applies in the specific context of gene technology. The remaining discussion will concentrate on how, or indeed if, the process of risk governance has been realised within the context of the *Gene Technology Act* 2000 (Cth) (GTA/the Act).

This chapter is dedicated to setting the groundwork upon which to undertake a GTA specific discussion. It will consider the core, explicit structures within the GTA that underpin deliberative risk governance, upon which all three pillars of that process derive – that is *making, doing and enforcing* the law. It will consider how these core structures will be built upon, in the practical 'soft law' frameworks that guide the day to day operation of the regime.

15.1 ESTABLISHING THE GUIDING PRINCIPLES

Approaching the Act in a balanced manner requires determining the degree of institutionalisation necessary to guarantee a participatory regulatory regime. Deliberative risk governance must be institutionally guaranteed through the creation of express legislative mechanisms. This was emphasised by the 1994 NHMRC Report [see above 11.6], which recommended that governmental risk communication practice should be underpinned by 'actual structural

mechanisms'.[1] Such mechanisms were seen as imperative to countermanding a natural power differential that arises between key agents in the deliberative risk governance process.[2]

Conversely, it must also be realised that 'cementing' contemporaneous principles into legislation can render the framework incapable of advancing or improving. Should the GTA have been enacted two decades ago, the form of risk communication accepted as practice at that time would have been quite different to the current vogue. As time went on, this approach would be open to increasing criticism and would require eventual regulatory review. Similarly, the current deliberative risk governance approach needs to evolve, and be capable of relevance in the face of a new standard accepted two decades on. There is then a tension between the need to maintain flexibility within legislation and the need to ensure that basic principles of risk communication are not derogated from.[3]

Regulatory flexibility must be tempered, so as to ensure that the conceptual and practical frameworks constructed by non-legislative bodies do not step too far beyond the desired purpose of the law. Hence, underlying the overall deliberative risk governance process must be fundamental guiding principles from which the conceptual and practical frameworks will not deviate. This is not a new concept; Parliaments have long sought to set out core overarching principles within preambles, objects clauses or in mandatory obligations upon decision makers.

The discussion over the next three chapters will examine the statutory risk communication mechanisms built into the GTA and how the conceptual and practical frameworks constructed by the Office of the Gene Technology Regulator (OGTR) have translated these mechanisms into practice. The remainder of this chapter will concentrate on the fundamental guiding principles that guide the construction process.

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[1] National Health and Medical Research Council, *National Framework for Environmental and Health Impact Assessment,* Commonwealth of Australia (AGPS), Canberra, 1994.

[2] *ibid.*

[3] This was also recognised in the 1994 NHMRC report, which recommended that 'structural mechanisms' are offset by the continued development of 'conceptual and practical frameworks to ensure that effective communication are actually realized'. *ibid.* p. 87.

15.1.1 INTERNAL GUIDING PRINCIPLES

The fundamental guiding principle in an Act is the objects and or framework clause.[4] In a regime with an independent and final decision maker, the next most important set of guiding principles should be found in the functions clause setting out that Regulator's powers and obligations. It is worthy of note, then, that neither the objects clause, nor the framework clause of the Act,[5] makes any mention of public participation, communication, transparency, accessibility or any other obligations to involve the community in the decision making process. Nor does the functions clause impose any express obligation to consult with or involve the public. It does, however, require that the Regulator provide 'information and advice to the public about the regulation of GMOs'.[6] This broad requirement is not further defined within the legislation. It would, on the whole, seem to be a unidirectional provision, limited in scope to one aspect of the deliberative risk governance process, namely process transparency.[7]

Finally, whilst there is express mention of risk assessment and risk management, risk communication is never referred to at any stage in the GTA, despite it now being accepted as a necessary component of the risk analysis paradigm [see 12.2]. The Regulator is, however, required to monitor international practice relating to, and maintain links with domestic and international organisations, dealing with the regulation of GMOs.[8] The resultant importation of risk communication principles

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[4] s.15AA, *Acts Interpretation Act 1901*(Cth). "In the interpretation of a provision of an Act, a construction that would promote the purpose or object underlying the Act (whether that purpose or object is expressly stated in the Act or not) shall be preferred to a construction that would not promote that purpose or object." The objects clause of the Act expresses Parliamentary Intention on how all provisions in that act are to be interpreted and applied, such that it narrows the jurisdictional scope of the Act. *(Wacando v Commonwealth* (1981) 148 CLR 1, 23 ; *Mason v Armitage* (1806) 13 Ves Jun 25; 33 ER 204, 208 *Powell v Kempton Park Racecourse Co Ltd* [1899] AC 143).

[5] ss. 3,4, GTA.

[6] s.27(f), GTA.

[7] Indeed as will be discussed below, the OGTR has interpreted this provision as obliging 'ongoing communication process about the work of the Regulator, through mailing lists, the Regulator's website and handling general public inquiries'.

[8] ss.29(g)-(k), GTA.

from these sources will be dealt with in chapter 17. However, I wish to first consider the implications of not expressly stating the importance of public involvement within the GTA itself.

Concern over Express Community Reference. During the debates the minor parties seized upon the lack of any express reference about the importance of community involvement. Senator Stott-Despoja, argued that:

> What mechanisms are available to inspire community confidence? … I use that terminology, 'community confidence', because I think that has to be the *underlying principle* [emphasis added] in this bill … I think that they have to be the underlying principles with which we approach this debate; that is, what is the purpose of this bill? Is it to inspire community confidence? Is it to provide for public awareness of and education about GM food, GM products and the release of GMOs into the environment or onto our supermarket shelves? [9]

The Greens subsequently tabled an amendment to the objects clause of the Act that they proposed read:

> … is transparent and encourages public participation in decisions concerning the development, use and release of GMOs and GM products.[10]

The minor parties voted for the amendment but were defeated by the Government and Opposition voting together. Unfortunately, the Greens amendment was coupled with a more contentious one relating to GM free zones.[11] Parliamentary discussion over the amendment concentrated solely on the GM free zone issue. Hence there is no clear statement as to why the two major parties refused to support the inclusion of an overarching statement about public participation in decision-making.

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[9] See *Senate Hansard*, pp 20423-20424.

[10] Brown B, '*Gene Technology Bill* 2000 …. Second Reading', *Senate Hansard*, 7/12/2000, p 21207.

[11] *ibid.*

Basis for Exclusion of Community Conferral. The Government and Opposition's position may be gleaned from a more general discussion about other sections of the Act (outside the objects clause), which occurred on the same day as the debate about the objects clause. The three minor parties all tabled amendments to existing sections of the Act that required the Regulator to ensure transparency and public participation in her or his various duties.[12] Both the Government and the Opposition opposed such measures as being unnecessary and 'overly prescriptive', arguing the spirit of the legislation already obliged such measures.[13] This position might also explain why the major parties rejected the Greens amendment of the objects clause of the Act.

The dismissal of any express statements relating to public participation, on the grounds that such statements were 'overly prescriptive', met with derision from the minor parties. The Greens described the 'overly prescriptive' argument as one without grounds or justification.[14] The Democrats argued that:

> claiming that there is a prescription … is a bit of a furphy and once again an attempt to ensure that there is minimal public involvement—not simply consultation but public involvement. I do not see the harm in it; it might actually see quite a few more Australians having some faith in the regulatory system, the regulator and the rules that we come up with.[15]

One Nation contended that the Parliament had an obligation:

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[12] These included express provisions for how consultation were to be conducted and with whom, notification obligations, publication requirements, content (translation of technical data) objectives, waiting periods in which to consider public submissions and citizen juries. See *Senate Hansard*, pp 20460, 20486 – 20500, 20572.

[13] See *Senate Hansard*, pp 20493, 20595.

[14] A typical discourse on adding detail to consultative requirements is set out as follows

Senator BROWN (Greens) —What is wrong with the words that I have added to that amendment?

Senator Tambling (Govt) —In our view they are unnecessary.

Senator BROWN—That is about the level of incisive response that I would expect from the government. It does not know what is wrong with that amendment. Those words do enhance the definition. I will not continue to debate the matter, but I think there is a little bit of the government simply saying, 'We will ignore any amendment that comes up here from the minor parties.' see *Senate Hansard*, 1/12/2000, p 20462

15 Stott-Despoja N. '*Gene Technology Bill* … Second Reading', *Senate Hansard*, 4/12/2000, p 20494.

> to see that it has the clarity and also the detail that give everybody an understanding — not only the regulator and the industry, but also the general public — as to how they can have an input into the process … the more this process is discussed at the local area level, the more we lift the awareness of the public and the right of the public to actually have an input into and a say on what they are consuming. So, for clarity, I believe the details are necessary.[16]

It must be reiterated that legislation cannot be overly rigid; it must provide the flexibility to allow for conceptual and practical frameworks to be built, moulded and torn down if necessary. Nevertheless, there is some weight in the minor parties' arguments, insofar as they relate to the lack of express guiding principles within the Act. This is not to say that the Act is devoid of structural mechanisms that underpin deliberative risk governance. They do exist and will be explored in the following chapters. Nevertheless, there is definitely an absence of provisions promulgating the need for community participation. The need for such a clear legislative statement is particularly strong given the perceived lack of inclusionary devices in the previous regime [see 13.3]. Such basic principles ensure that the conceptual and practical frameworks are constructed in a manner accordant to the intention of the enacting Parliament. Equally importantly they make a decisive statement about the value of the community within the Act.

15.1.2 EXTERNAL GUIDING PRINCIPLES

Whilst there is no express statement as to the importance of community involvement, nor the obligation to ensure the community is involved within the GTA, such principles may be imported into the Act from external sources. Section 15AB of the *Acts Interpretation Act* 1901 (Cth) allows reference to extrinsic materials, particularly those which relate to legislative history, in the ascertainment of the meaning of provisions of an Act. Four extrinsic sources

16 Harris, '*Gene Technology Bill* … Second Reading', *Senate Hansard*,, 4/12/2000, p 20494

referred to in the Acts interpretation act, which may assist the current discussion, are:

- reports or inquiries made by a committee of either house of parliament into the Act (section 15AB(e));
- any explanatory memorandum set out to parliament. (section 15AB(e));
- the second reading speech by the relevant Minister to either house of Parliament(section 15AB(2)(f)); and
- any part of Hansard with reference to the Act. (section 15AB(2)(f)).

All of these documents, as they relate to the GTA, place extensive emphasis on the importance of community participation and transparency.[17] The Explanatory Memorandum is particularly emphatic about the Government's intention to include the community in the process of regulating. The Memorandum states that the GTA regime should 'instil public confidence in the regulatory system' and the 'essential' way of achieving this aim is to ensure that 'as much information as possible is made available to the community'.[18]

In outlining the objects clause of the Act the explanatory memorandum notes that:

> Against the Government's broad goal [of protecting human health and the environment], and to address the shortfalls in the current regulatory arrangements, the Government's objectives are to … achieve greater transparency and accountability; and be more responsive to stakeholders and community views …[19]

In order to achieve these aims the Government intended the Act to guarantee:

> a high level of transparency and stakeholder involvement in decision making that risks are effectively communicated to consumers and others to allow them to make informed decisions on the basis of all the facts. Effective risk assessment and communication by the Regulator reduces potential imbalance in

[17] For reference to community consultation and transparency in Parliamentary reports see chapter 14 .

[18] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra, p 29.

[19] *ibid*, p 12.

> the market place. This occurs where, for example, information is unavailable to one party (i.e. consumers/the public).[20]

Hence, all aspects of deliberative risk governance are promoted as core principles by the explanatory memorandum and these may be used to direct the application of various sections of the Act. However, recourse to documents such as the explanatory memorandum is limited, not least because the High Court has advocated caution in the use of section 15AB of the *Acts Interpretation Act.*[21] Furthermore section 15AB is predominantly oriented towards the clarification of individual sections or words within an Act[22] and less about clarifying guiding principles that underpin an Act as a whole.[23] However, prior to the section 15AB amendment, courts accepted extrinsic materials to determine the underlying purpose of the legislation.[24] Whether these rules have survived this amendment has not been tested in the High Court.[25]

Intergovernmental Agreement . In order to ensure a national approach to legislation the States and the Commonwealth have signed an Intergovernmental Gene Technology Agreement (the Intergovernmental Agreement) [see 4.1]. The Intergovernmental Agreement is intended to achieve national consistency, set out the respective obligations of the Commonwealth and the States and establish the Ministerial Council for the purposes of the Act.[26]

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[20] *ibid*, p 38.

[21] In *Re Bolton* [*Re Bolton; Ex pare Beane* (1987) 70 ALR 225], the court warned that 'the words of a Minister must not be substituted for the text of the law.' See also *Australian Broadcasting Tribunal v Bond Corp Holding Ltd* (1989) 86 ALR 424 at 429; *Minister for Immigration and Ethnic Affairs v Tang Jia Xin* (1994) 74 A Crim R 59.

[22] So, extrinsic materials may be looked to, either to clarify that the meaning is an everyday meaning or to clear up an absurdity or anomaly created by the wording of a section[subs.15AB(1)(a)15AB(b), *Acts Interpretation Act 1901* (Cth).

[23] See *Brendan v Comcare* (1994) 122 ALR 615 per Gummow J at 634, *Brooks v FCT* (2000) 173 ALR 235 at 253.

[24] *Dungan v Mirror Newspapers Ltd* (1979) 22 ALR 439 at 452 ; *TCN Channel Pty Ltd v Australian Mutual Provident Society* (1982) 42 ALR 496. *Owen v South Australia* (1996) 66 SASR 251, *Commr of Taxation (Cth) v Whitfords Beach Pty Ltd* (1982) 39 ALR 521 at 533-4.

[25] For a discussion on this matter see Pearce D, Geddes R, *Statutory Interpretation in Australia*, Butterworths, Sydney, 2002 p 61.

[26] ss.10(2), 14(3), GTA, Part 3, *Gene Technology Agreement*, Between The Commonwealth And The States And Territories, Effective As Of 11 September 2001, the agreement can be found at,

One of the core principles outlined in the Intergovernmental Agreement is that 'the scheme should be characterised by decision-making that is transparent, and that incorporates extensive stakeholder and community involvement'.[27] This is a much more resolute commitment to community involvement than can be found within the Act proper. It is worthy of note that the Agreement does not only refer to transparency, but envisages that the community be 'involved' in decision-making.

The Intergovernmental Agreement is a cornerstone of the overall GTA regime and thus can be seen to create a guiding principle, at least in regards to the States, the Minister and the Ministerial Council. There is however cause to question the exact extent to which it binds the Regulator, or the OGTR for that matter. The Agreement is only mentioned within the Act in respect of the latter-mentioned parties, not the Regulator or her/his Office. Under the Act, the Regulator is not required to comply with the provisions of the agreement. Given the degree of independence the Regulator has from Ministerial control [see 9.2.1], the binding nature of an agreement between Ministers of the Commonwealth and the States is questionable. Indeed, for the purposes of administrative enforceability, it is unlikely that a provision such as the one mentioned above could be seen to bind the OGTR at all. The Agreement would appear to form more of a contract between parties, of which the OGTR is not a member, rather than binding administrative law.[28]

Questions as to the legal status of intergovernmental agreements have arisen previously, for instance, in relation to the seminal *Intergovernmental Agreement on the Environment (*1992) (IGAE). Like the Intergovernmental Gene Technology Agreement, IGAE is designed to implement a national approach in an

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<http://www.health.gov.au/tga/gene/iga010209.pdf> (3/3/03). [hereafter Intergovernmental Agreement].

[27] Recital B.(f), Intergovernmental Agreement.

[28] Although of course, should an issue of administrative enforceability arise, the emphatic statements in the Explanatory Memorandum would no doubt be imported, as discussed above.

area with unclear constitutional limits and both agreements are based on the same fundamental framework.[29]

The IGAE has been described as 'soft law' and some have argued that 'it is clear that [the Agreement] is not intended to constitute a binding legal document so much as a statement of intent or aspiration'.[30] However, others have received the IGAE as 'a great rationalisation and reception of sustainability principles in Australia in a formal policy and jurisprudential sense'.[31] I would tend to agree with the latter argument. As that author (Evans) notes, the IGAE may have 'less than desirable' legal status,[32] but it does constitute a clear, formal statement of all levels of Government's commitment to legislating with certain core principles in mind. Whilst it is arguable as to whether it binds the Regulator in any practical sense, it certainly constitutes a strong policy directive that would not be easily abrogated without attracting unwelcome review and criticism from outside.

15.2 THE COMMUNITY CONSULTATIVE COMMITTEE

One of the most dominant community oriented mechanisms within the GTA regime is the Gene Technology Community Consultative Committee (the Community Committee). Without becoming overly semantic, this body could be considered both a 'structural mechanism', given its institutional status within the Act or a 'guiding principle', because its mere existence connotes a commitment to 'consult' with the 'community'. Regardless of how it is described, it is relevant to the current discussion because it has a role in the overall deliberative risk governance process (*making, doing, enforcing*). Thus, the Community Committee is introduced here because it is a common feature to all aspects of deliberative risk governance. This discussion also provides a broader picture of the role of the

[29] For instance, both contain short recitals and separate operational sections and schedules which outline application and interpretation, roles of the parties, general principles, review etc. See Sections 1-5 and schedules 1-9, Intergovernmental Agreement on the Environment 1992.

[30] Bates G, *Environmental Law in Australia*, Butterworths, Sydney, 1995, p 35. see also Gardner A, 'Federal Intergovernmental Co-Operation on Environmental Management' (1994) *Environmental Planning and Law Journal* **11**:119.

[31] Evans M, *Principles of Environmental Heritage*, Prospect, Sydney, 2000, p 167

[32] *ibid.*

community within the GTA regime. The following chapters will consider the role of the Community Committee within the context of each pillar of deliberative risk governance.

As stated previously the original Gene Technology Bill contained no Community Committee [see 14.3.1]. After recommendations from the Consensus conference the Government introduced a third body entitled the Gene Technology Community Consultative Group[33] that would 'consider matters of general concern' and 'inform policy development and regulation'.[34] Following recommendations from the Senate Committee [see 14.4.3] and subsequent Senate debate, the profile of this 'group' was strengthened to committee status. The Act now specifies that the Community Committee *must* be consulted in relation to policy principles and codes of practice.[35] The Community Committee *may* also be called upon to provide advice on 'matters of general concern in relation to GMOs' and the need for policy guidelines, technical and procedural guidelines in relation to GMOs and GM products.[36]

Ideally, the Community Committee will act as a contact point between the OGTR and various sectors of the public. This was the role conceived for it by the Lay Panel of the Consensus Conference, which hoped it would lead to deliberative decision making and 'bring together all stakeholders to talk to each other to reach agreement on mutually beneficial solutions'.[37] The Committee promises to fulfil an important function in making the GTA an integrative system, able to capacitate various community concerns. The question is how it will do this effectively and realistically in an ongoing sense.

An Indefinite Agenda. The Act provides little in the way of terms of reference for the Community Committee. Its role appears to be to provide advice on matters of

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[33] Interim Office of the Gene Technology Regulator, *How Outcomes Of The First Concensus Conference On Gene Technology In The Food Chain Are Being Addressed*, Commonwealth of Australia (AGPS), Canberra, 2000, p 10. .

[34] *ibid.*

[35] subs.22(1)(c) and 24(2)(c), GTA.

[36] subs.107 (a) & (b) GTA.

'general concern' – a rather non descript charge. Neither the Gene Technology Regulations nor the Intergovernmental Agreement on Gene Technology expand upon this role.

The Committee's title could perhaps be construed as a directive, in that it necessitates the Committee 'consult' with the community.[38] What it does not answer, is how or when such a consultation should take place, the extent of that consultation and how community concerns will feed into the system. Indeed, outside the Committee's title there is no mention of consultation within the Act. Nor is there any specific obligation upon the Committee to even maintain a dialogue with the greater community.

No Lay Members. In line with the recommendation of the Lay Panel, the Interim OGTR stated that the Community Committee would reflect the 'broad interests of the general community' by being constituted of 'industry, consumer representatives, critics, other experts and *Australian lay people* [emphasis added]'.[39] The final committee, however, lacks any lay representation.

The GTA requires that *all* members of the Community Committee have 'skills or experience in gene technology' within specific fields, including the environment, industry, research and health issues. Having skills and expertise, and being from a specific profession would seem contrary to the definition of a 'lay person'.

As was noted above [see 13.1], dealing with the community as if it is a unified entity, fails to recognize that in fact there are diverse 'interested communities'. Thus, representing key members of interested communities provides a more accurate picture of the broader social and political views regarding gene technology. Yet, the original vision of the Community Committee was a body that

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[37] *First Australian Consensus Conference Gene Technology In The Food Chain*, Lay Panel Report, The Australian Museum, Canberra, 1999, <http://www.austmus.gov.au/pdf/layreport.pdf> (10/10/02), p 6.

[38] On the other hand it could be read that the committee is representative of the Community and the Regulator is meant to 'consult' with the Committee.

[39] Interim Office of the Gene Technology Regulator, *How Outcomes Of The First Consensus Conference On Gene Technology In The Food Chain Are Being Addressed*, Interim Office of the Gene Technology Regulator, Canberra, 1999. p 10.

would represent and include 'Australian lay people'.[40] It seems rather strange that the scientific committee would have one lay person, yet the Community committee should have none.

No Lawyer. Given the Committee is made up of 'experts', rather than lay people, there is cause to question why there is no requirement that a lawyer or at least a legally trained committee member be empanelled. As so much of the Committees role will involve legal matters, not least of which will include regulatory communication, it would seem imperative that a lawyer be involved, particularly when considering the legal complexities of the Act.

No Right to Advice. Whilst the Minister may appoint expert Advisors to both the Ethics Committee and the Technical Committee,[41] no such provision is made for the Community Committee. This is strange given that the community committee is likely to have the least expertise in specific fields regarding genetic technologies. The Act does not make provision for the Committee to specifically request an expert. Nor is there a process by which the Minister should respond to a request for an expert witness. There appears to be no obligation upon the Minister to ensure that expert advisers be appointed to fill deficiencies, such as legal training, for situations requiring that expertise.

The Community Committee was a late addition to the GTA, which may be the reason that it appears to be lacking in a clear directive and structure. The preference for minimalist legislative prescription by the Government, as evidenced from the discussion above [see 6.2] may also have a large part to play in the skeletal nature of its terms of reference. Moreover, the introduction of Biotechnology Australia's 'public awareness' arm [see above 14.3.2] may have also contributed to the reluctance to over-extend the role of the Community Committee into what became 'non regulatory' matters. Therefore, whilst the importance of this Committee cannot be understated, it does – at least from the outside – appear a powerful concept that lacks powerful underpinnings.

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[40] *ibid.* Stott-Despoja N, '*Gene Technology Bill* 2000 … In Committee', *Senate Hansard*, 1/12/2000, p 20424.

[41] ss.102,113, GTA.

15.3 CONCLUSION

The short but turbulent history of gene technology in Australia gave rise to demands for process legitimacy. Key to the call for reform was the perceived exclusion of the community from the decision making process. Recognising this, the Government instituted a comprehensive overhaul of the existing frameworks to satisfy community demands. Importantly, the process of overhauling that framework was done in partnership with the community and key stakeholders. It was undertaken in an environment of deliberation and multi-directional communication. This accorded to an 'ideal' deliberative risk governance process.

It is a jarring note then, that the concept of community participation, so central during drafting, was not included as a central principle in the regime itself. Indeed, it would seem, at least superficially, that, once the GTA came into operation, the community moved out of the process of making law and merely became the subjects of the law once more.

Outside of the unidirectional requirement to 'inform the public' about the process of regulation, there can be said to be no overarching obligation within the Act to ensure community participation. Likewise, the body established to oversee community consultation and stakeholder participation lacks any clear directive as to how it is to operate. There is then an inherent lack of prescription in the Act on the notion of deliberative risk governance.

As discussed in this chapter, certain guiding principles can be derived from external, incidental legislative sources. These make it clear that the OGTR *is* expected to consult with community and stakeholder groups and to actively foster participation by these parties in the process of risk governance. Furthermore, as will be discussed in the succeeding chapters, there are basic structural mechanisms built into the Act that guarantee some degree of deliberative risk governance.

If indeed the Government intended the community to be of central importance to the ongoing process of risk governance, it must be questioned why this ideological commitment does not receive expression within the Act, as did the objects of protecting human health and the environment. There is no denying those objects are of core importance to the success of the regime, both in protecting the public and ensuring its support. Yet, those objects were already implemented under the GMAC regime. GMAC was a body whose *sole* purpose was to consider the ecological and health impacts of gene technology. Whilst its demise was partially related to it not 'having teeth', it was equally prone to attack because of its perceived lack of transparency, inclusiveness and community deliberation. GMAC may have 'protected the public' but it certainly did not 'ensure its support'.

There would seem little to lose from enshrining public participation and transparency in the objects clause of the Act, or to proscribe that the Regulator consult with the public. In fact, the inclusion of such provisions would have gone a long way to increasing community trust, by providing a clear, unmistakable declaration of the importance of community input to the decision making process.

Without the implementation of fundamental guiding principles, the legislation contains little direction on how deliberative risk governance is to operate in practice. This means that a great deal of the process of actually legislating falls to unelected internal working groups which are required to fill in gaps (some might say gaping holes). It also means that bodies such as the Community Committee must, to a certain extent, set their own agendas because they have less than adequate terms of reference. Just how this affects the actualisation of deliberative risk governance will be dealt with over the next three chapters.

16

MAKING LAW: PUBLIC INVOLVEMENT AND REGULATORY COMMUNICATION

It has long been recognised that 'new ideas in the form of draft bills are brought to legislators by citizens, scholars, lawyers, bureaucrats, and lobbyists'.[1] There is also an increasing recognition that these groups cannot be suddenly estranged from the regulatory process simply because those draft bills have been formalised into active legislation. Those stakeholders and community members who first conceived of the conceptual legislative framework are in the best position to reflect on whether the actual framework achieves what was intended. Add to those groups those affected by the application of a legislative regime and you achieve an extremely powerful review body. The importance of this body in a technological risk regime is multiplied, because of the ever-changing subject matter of the law.

Regulating novel risk is an ongoing process, in which the regulatory system must be continually evaluated, scrutinised and adapted to capacitate a constantly shifting subject matter. Continued regulatory communication is, then, imperative because it ensures that the law cannot 'go stale', become redundant or allow loopholes to develop with the inception of new technology. Continued deliberation is equally critical to *maintaining* public trust, because by involving the community in risk governance they can see that risks are being sufficiently attenuated. In an ideal deliberative risk governance model this means including all

[1] Davies J, *Legislative Law and Process* 2nd ed, West Publishing, Minnesota, 1986 p 3.

interested and affected parties in the ongoing formulation, review and scrutiny of regulation to existing and new risks.

Chapter 14 dealt with the process of regulatory communication prior to the implementation of the *Gene Technology Act* 2000 (Cth) (GTA/the Act). This chapter examines how the processes for community involvement in legal and policy development were continued on into the 'legislative regime' itself. As stated above, such involvement is important because the very architecture that establishes a risk governance regime must be subject to interactive deliberation. The discussion in chapter 14 also revealed that the only internal guiding principle relating to community involvement was the obligation to inform the public about gene technology regulation. Hence regulatory communication – at least in a unidirectional sense – is the only express internal guiding principle within the Act. This chapter examines the extent, efficacy and commitment to that principle.

In examining the process of regulatory communication within the Act, this chapter will cover:

- *The Clarity of the Risk Regime.* That is, whether the law itself is understandable and open enough to ensure that the general community can contribute to its reform. If it is not, then what mechanisms have been put in place to assist a better comprehension of the system by the lay public.
- *Processes & Policy Mechanisms.* Those mechanisms, structural and conceptual frameworks for community input into internal regulatory mechanisms, which shape the standard setting process (codes of practice, policy principles etc).
- *Review Mechanisms.* Whether the process of consultation and participation in the law ceased with the *enactment* of the GTA or whether there are institutional guarantees that the public will be further involved in formalised legislative review.

16.1 CLARITY OF THE RISK REGIME

One of the most fundamental prerequisites for community involvement in regulatory communication is ensuring that all affected parties understand the law. If the overall regime proves overly complex, confusing or unworkable, many will be unable or unwilling to participate in either the law or its reform. Misconceptions about the ambit, purpose and application of that law may arise. The obvious outcome of such confusion will be the diminution of trust by those left frustrated by legislative complexities.

In terms of regulatory communication, overly complex legislation may preclude those without adequate resources from participating in its review. The larger the audience which understands the law, then the greater the number of contributors to a discussion on how to improve and refine it. Equally importantly, the more involved the community is, the less likelihood that some groups will dominate, or be perceived to dominate, the overall communication process.

The issue of comprehension is a subjective one, because, as Penfold argues, legislation must cater to:

> a variety of different audiences, each individual member of which brings to the process of interpretation a unique set of pre-conceptions, life experiences and understanding of language.[2]

16.1.1 AUDIENCE AND LANGUAGE

The Office of the Gene Technology Regulator (OGTR) and relevant government agencies both at State and Commonwealth level need to have a working understanding of the Act. Large multinational gene technology companies, are likely to have associated legal departments to deal with the legal aspects of their ventures, or ready access to legal counsel. Universities, Research Organisations and Private firms also tend to have the resources to invest in legal counsel to interpret the provisions of the Act. Yet, as the vast number of submissions to the various inquiries involved in the drafting of the Gene Technology Bill indicate,

[2] Penfold H, 'The Genesis of Laws' in *Courts in a Representative Democracy*, AIJA, Melbourne, 1995, p 41.

there are a wide range of other parties who have had and will continue to have an interest in the regime. These may include small-scale industry, farmers, consumer and environmental groups, journalists and members of the public.[3] Many of these groups are unlikely to be legally trained or have large amounts of resources to invest in legal advice or assistance.

The regulatory challenge is to create law that, as far as possible, brings these various audiences together so that there is a consistent and mutual understanding of what the law *actually* means. A regulatory agency with sufficient resources, sufficient willpower and expertise could potentially undertake a multi-message communication strategy, so as to engage these various audiences. From the experiences outlined above, this may not always be realised. Indeed, the point of deliberative risk governance is to move beyond mere strategies and ensure that certain fundamental communication mechanisms are entrenched into the legislation itself. Thus, legislation must be tailored to capacitate those groups and individuals who will utilise, contribute to and participate in the overall regime.[4]

The Use of Plain English Drafting. To assist those without legal expertise, there has been a move over the last few decades towards using 'plain english' language in preference to unnecessary complex or technical terminology or structure.[5] This policy has been premised on a need to improve access to justice for the majority of the population.[6] It requires that drafters temper the language, sentences, structure and layout of the statute towards the layperson rather than the expert.[7] Ensuring that legislation is as uncomplicated as possible effectively

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[3] see Appendix 3.

[4] "This principle simply ensures that the mechanism will be understood by those who are affected by it". Office of Regulation Review, *A Guide to Regulation*, 2nd Ed, Commonwealth of Australia, Canberra, 1998, p 15.

[5] House of Representatives Standing Committee on Procedure, *Time For Review: Bills Questions And Working Hours -Report Of The Review Of Procedural Changes Operating Since 21 February 1994*, Commonwealth of Australia (AGPS), Canberra 1995.

[6] Mason S 'Law-making, drafting and law reform' in *Essays on Legislative Drafting,* Adelaide Law Review Association, Adelaide, 1988, pp 112-113.

[7] House of Representatives Committee on Legal and Constitutional Affairs, Clearer Commonwealth Law: Report of the Inquiry into Legislative Drafting by the Commonwealth, Commonwealth of Australia (AGPS), Canberra, 1993. Ch 7.

minimises the amount of resources required to undertake a deliberative communication process, because the law becomes, of itself, more accessible to a general audience. There is less need for experts to intervene, so as to communicate the meaning of the legislation or its provisions.

The GTA includes 'simplified outlines' to each of its sections preceding each division. These describe the basic premise of the division, what it is intended to accomplish and how it is meant to operate. It also contains explanatory notes to refer the reader to the applicability of other State or Commonwealth Laws. Most importantly the Act and the Regulations are, on the whole, written in 'plain English' and avoid overly legalistic or scientific language except where entirely necessary (for instance the regulatory provisions outlining the quantities of genetic material acceptable for certain dealings). The various provisions within the GTA reflect best practice in legislative drafting by the Commonwealth.[8]

Size of the Scheme. Language is not the only barrier to accessibility. The size of a body of rules, its complexity or logicality can also create impediments to the lay person and increase the costs of legislation.[9] Indeed the size, complexity and logicality of the Act and its subordinate regulations are of great concern. The GTA, along with the *Gene Technology Regulations 2000*, *Gene Technology (Consequential Amendments) Act 2000* and *Gene Technology (Licence Charges) Act 2000*, totals some 237 pages. There are also a number of State Acts, some released and some pending.[10] Furthermore the *Intergovernmental Agreement on Gene Technology* must be considered relevant to how the regime will operate, particularly with reference to the States.

This system of comprehensive primary and delegated-legislation requires constant cross checking between Act and Regulations. Moreover, the Act is but a 'gap

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[8] *ibid.* also Australian Law Reform Commission, *Managing Justice*, Report No. 89, Australian Law Reform Commission, Sydney, 2000 4.56-4.61.

[9] Between 1973 and 1991 there was a 325% increase in the volume of Acts produced. Between 1980 and . 1991 there was a 262% increase in subordinate legislation. McHugh M, '*The Growth of Legislation and Litigation*' (1995) *Australian Law Journal* 69:38.

[10] Currently Victoria, South Australia and Queensland are listed as having enacted complementary legislation by the OGTR on its website < http://www.ogtr.gov.au/pubform/legislation.htm> (21/11/04).

filler' coexisting with other State and Commonwealth Acts, which must also be cross checked [see 4]. In all there is a mass of legislation, regulations, rules, guidelines, policies and other documentation that must at different stages be referred to when considering dealings with GMOs. This is a daunting task, even to the legal expert. What then of the layperson who wishes to understand the scheme? From a legal perspective this complexity is unwelcome, because at the very least an individual should have a general understanding of their rights, or indeed lack of rights, without recourse to legal or expert counsel.

16.1.2 MAKING THE REGIME MORE UNDERSTANDABLE

Whilst it is recognised that the form of the GTA regime is likely to exclude some groups from effective engagement, at least in the absence of expert intervention, there is reason to question just how simple it could have been made. The need to cater for a variety of audiences cannot undermine the integrity of the Act. Gene technology is both a broad and complex technology and will necessitate mechanisms able to respond to and deal with this subject matter. When given such a subject matter it will not always be possible to tailor the legislation to every audience. The inability to cater to every audience should not derogate from the overall principle of open access. Where it is impossible to make the legislation as clear as would be liked, mechanisms are necessary to ensure that those disadvantaged are adequately catered for.[11]

Explaining the Act. The only express mechanism regarding regulatory communication within the GTA relates to the functions of the Regulator. This provision obliges the Regulator to provide 'information and advice to the public about the regulation of GMOs'.[12] The breadth of this requirement is not extrapolated upon in the legislation and it is unclear to what extent the process of regulation must be explained or to whom. The OGTR has so far released:

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[11] Consider for example, Child Welfare Legislation. In such an instance, one group affected by the legislation may be incapable of understanding the complexities or legalities set out under the legislation. An official would be necessary to explain the nature of the law and the effects it would have to that child.

[12] s.27(f), GTA.

- The *Handbook on the Regulation of Gene Technology in Australia.*[13] This is intended to provide clarification on the requirements of the GTA to 'organisations that conduct work with GMOs'.[14]
- The *Risk Assessment Framework for License Applications to the Office of the Gene Technology Regulator.* This is intended for the use of applicants and those with 'an interest in the potential for and assessment of, risks from GMOs'.[15]

The OGTR further publishes 'Monitoring and Compliance Unit Protocols', to 'provide organisations and interested parties with guidance on monitoring and compliance activities'.[16] The office notes that, such protocols 'are under continual improvement' and will 'evolve as systems'.[17] Public comment is invited on the information provided. So far, this information relates to; monitoring and compliance; spot checks; accredited organisations compliance management systems; risk analysis, review, mapping; audit; non-compliance and allegations protocols.

Other documents available on the OGTR website include short one page summaries of various provisions of the Act, including:

- What is Biotechnology? - What is Gene Technology?;
- The GMO Regulatory System ;
- The Gene Technology Regulator, the Ministerial Council and the three Gene Technology Committees ;
- Public Participation in the Assessment of Gene Technology; and
- The Record of GMO Dealings and GM Products.

The OGTR has taken the obligation to inform and advise the public on the regulation of GMOs seriously. It has released a large amount of information relating to the regime in the relatively short time it has been in operation. This

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[13] Available from the OGTR website <http://www.ogtr.gov.au/pubform/handbook.htm> (7/8/02)

[14] *ibid.* p 8

[15] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001.

[16] OGTR website < www.ogtr.gov.au/moncomp/protocol.htm> (3/12/02).

[17] *ibid.*

information is designed to cater to various audiences and covers different aspects of the risk governance process. Perhaps the only criticism of the information released thus far is that, in lieu of legislative review [see 16.3] an updated explanatory guide to the GTA proper may be necessary as the above documents tend to refer to general provisions of the Act rather than individual sections. This would ensure that full and proper deliberation on individual components of the Act could be undertaken by all parties involved.

16.2 PUBLIC INPUT INTO PROCESSES AND POLICY

Explaining the provisions of the Act is an important first step towards accessibility, but to make the process of regulating truly participatory there must be mechanisms which ensure public input and scrutiny of the regulatory process itself. Because of the less than prescriptive nature of modern bracket shifting legislation such as the GTA, public involvement must go beyond legislative deliberation [discussed below]. It must allow *rule* deliberation, that is input into the 'soft law' processes and policies that direct the practical day to day operation of the regime.

The importance of input into regulatory process and policy was recognised early in the drafting process as the skeletal nature of the legislation was becoming clear. The Commonwealth-State Consultative Group on Gene Technology (CSCG), emphasised that it would be 'vital' to ensure that:

> all processes are open to public scrutiny [and] the public [must be] able to have a say in the formulation of gene technology policy. [18]

In promising such a level of openness and public input the CSCG was committing to a very active, ongoing and involved level of regulatory communication.

To effectively ensure multi-directional communication and input into the gene technology policy requires an awareness of the 'subtext' of the regulatory process

[18] Interim Office Of The Gene Technology Regulator, *Proposed National Regulatory System For Genetically Modified Organisms – How Should It Work?*, Commonwealth of Australia (AGPS), Canberra, 1999, p 36.

and the day to day operation of the regime. This means maintaining a clear line of communication between the regulatory agency and those involved in the scrutiny of the regulatory process to ensure mutual understanding of: what is working and what isn't; what challenges there were to the realisation of regulatory goals and what practical problems are envisioned in the future. It also requires a much more continual process of involvement over the course of regulating, as opposed to mere periodic review. Finally, because the soft law documentation underpinning the regime tends to have a great deal of scientific and technical detail – for instance in specifying risk assessment and management criterion – there is a need for multi-message knowledge translation to ensure all parties are raised to the same knowledge benchmark. [19]

Ensuring public input into the processes and policy underpinning the regulatory regime is then a massive ongoing undertaking. Yet it is an extremely important one because these soft law mechanisms dictate so much of how the regime operates in practice. Recognising this and the challenges to effective rule deliberation the CSCG proposed a holistic approach to involving the public at this level. This approach would use three main communication nexus points to ensure multi-directional dialogue. Using these would ensure that there was an ongoing communication stream that was neither cumbersome nor overburdening to the ongoing regulatory activities of the OGTR. These input points were :

- scrutiny, review and input into process and policy by the Community Committee ;
- public consultation on policies, standards and codes of practice; and
- direct engagement of the community through forums and target consultations.[20]

[19] As the Regulator states. "there are a range of people who will be consulting these documents from real technical experts through to people who have no technical expertise so what we have tried to do is layer the information in [Risk Assessment and Risk Management Plans] more recently". Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.

[20] Interim Office Of The Gene Technology Regulator, *Proposed National Regulatory System For Genetically Modified Organisms – How Should It Work?*, Commonwealth of Australia (AGPS), Canberra, 1999. p 35-37.

Together these should have ensured that there was a degree of public scrutiny and input at all levels of regulatory practice. This section will examine how and if this holistic approach was put into practice within the GTA regime itself.

16.2.1 THE COMMUNITY COMMITTEE'S ROLE IN REGULATORY COMMUNICATION

The most prominent mechanism introduced by the CSCG into the GTA to ensure public input into regulatory practice was the Community Committee. By entrenching a committee whose specific mandate was to represent sectional interests within the community the Government was evincing a willingness to work together with 'all stakeholders' and find 'mutually beneficial solutions'.[21] Yet, as outlined previously, there is a marked lack of prescription within the Act about the purpose, role or processes which are to underpin the Community Committee [see 15.2]. Consequently, the first meetings of the Community Committee were dedicated to determining its own purpose and role within the regulatory framework.[22] At its third meeting, the Committee wrote to stakeholders advising them of its presence and inviting comment on the regulatory consultations undertaken by the Regulator[23] and promised to continue to look for opportunities to interact with stakeholders in that area.[24] However, apart from this initial step towards broader engagement the Committee has adopted a role as a predominantly an internal expert review body.

Most of the Community Committee's regulatory communication activities are oriented around interaction with either the Regulator or the other two committees. This involves either face to face presentations on regulatory work and policy development by expert representatives or requests for review of existing documents. Thus far, the Community Committee has:

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[21] *First Australian Consensus Conference Gene Technology In The Food Chain*, Lay Panel Report, The Australian Museum, Canberra, 1999, <http://www.austmus.gov.au/pdf/layreport.pdf> (10/10/02), p 6.

[22] Gene Technology Community Consultative Committee Meeting, *Communique of 1st and 2nd GTCCC Meeting 17 - 18 April and 15 - 16 July 2002*, Office of the Gene Technology Regulator, Canberra, 2002.

[23] Gene Technology Community Consultative Committee Meeting, *Communique of 3rd GTCCC meeting 19 November 2002*, Office of the Gene Technology Regulator, Canberra, 2002

[24] *ibid.*

- reviewed the content and useability of the OGTR website and provided ongoing input into ways to improve access to it;[25]
- examined the form and content of notification, invitations to comment and risk assessment and management plans, and made comments accordingly;[26]
- scrutinised and commented on *Risk Assessment and Risk Management Plans* to establish whether they 'improved public communication and enhanced transparency of the regulatory process';[27]
- considered the Ethics Committee paper *Managing Risk Ethically* and provided comments;[28] and
- contributed to the review and development of the *Risk Analysis Framework.*[29]

These various contributions to the ongoing process of regulating risk indicate that the Community Committee has taken up an important representative role within the overall regime. In providing such advice the Committee is ensuring that informed and considered community perspectives are being communicated to the Regulator, OGTR and other committees. This places community representatives at the heart of the system to ensure that they contribute to and are consulted on the development of internal policy and practice. Furthermore, they are ensuring that the accessibility, transparency and inclusivity of the processes adopted by the regulatory agency are evaluated from a public perspective not a technical or scientific one.

The Community Committee has a direct input into the OGTR, but what input does the community have into it? As of yet, the Committee has had minimal public

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[25] Gene Technology Community Consultative Committee Meeting, *Communique of 3rd GTCCC meeting 19 November 2002,* Office of the Gene Technology Regulator, Canberra, 2003.

[26] Gene Technology Community Consultative Committee Meeting, *Communique of 3rd GTCCC meeting 19 November 2002,* Office of the Gene Technology Regulator, Canberra, 2003.

[27] Gene Technology Community Consultative Committee Meeting, *Communique of 5th GTCCC Meeting 5 June 2003,* Office of the Gene Technology Regulator, Canberra, 2003.

[28] Gene Technology Community Consultative Committee Meeting, *Communique of 7th GTCCC Meeting 29 April 2004,* Office of the Gene Technology Regulator, Canberra, 2004.

[29] Gene Technology Community Consultative Committee Meeting, *Communique of 8th GTCCC Meeting 4 August 2004,* Office of the Gene Technology Regulator, Canberra, 2004.

interactions, despite the fact the OGTR has considered literally hundreds of licence applications. In the single case where the Committee has gone out into the public arena it met with experts, industry, government and key stakeholders in the Mount Gambier region. The purpose of this expedition was to inform *itself* about the way that gene technology was being regulated in the field, not to undertake any outreach or engagement work of its own within the area. Hence the Committee has adopted a role which is inward looking and its communication methodology is not output oriented.

The role of the Committee as an internal review body does not ride against either the Consensus Conference's vision or the CSCG's promise [see 14.3.1]. To reiterate it was the Lay Panel's contention that a mechanism should be introduced to 'bring together industry, consumer groups, critics, other experts and Australian lay people', to ensure that 'dialogue between all of these groups would lead to better government decisions'.[30]

Certainly the Community Committee is representative of various sectional interests gene technology. Yet the ten members of that Committee cannot purport to be representative of the community as a whole or the diversity of interests in it. For instance there are no organic farmers, food manufacturers or distributors represented on this Committee. Whilst the committee members who are there undoubtedly are capable of understanding and sympathising with such constituencies they cannot be said to be representative of them. Nor, as an expert body, without representation from 'Australian lay people' [see 15.2] can the Committee be said to represent the mainstream or lay view of certain issues relating to gene technology.

Because all members of the Community Committee have an expertise in gene technology or the regulation of gene technology [see 15.2] they will not be approaching aspects of transparency and accessibility from a completely lay point of view. As the Committee becomes ingrained in the system and increasingly familiar with technical regulatory practice there is a potential for it to lose much

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[30] *First Australian Consensus Conference Gene Technology In The Food Chain*, Lay Panel Report, The Australian Museum, Canberra, 1999, <http://www.austmus.gov.au/pdf/layreport.pdf> (10/10/02), p 6.

of its ability to take on the mantle of a community representative body. It would seem important then for the Committee to maintain a degree of interactivity with the broader community.

Just as it can be asked why there is minimal public input into the Community Committee it might also be asked why the Committee does not output information to the public. Biotechnology Australia's assumption of responsibility over communicating about regulatory mechanisms and risk governance [see 14.3.2] has removed much of the motivation to adopt such a role – something discussed below in relation to the OGTR proper [see 17.2.4]. Furthermore, the Committee only meets two or three times a year, which leaves it little time to undertake extra activities. This is of course something that could be remedied by extra funding, time allocation or community engagement by sub-committees or individuals who could report back to the Committee proper. Part of the benefit of having the Community Committee within the overall GTA framework is the expression of a willingness to involve and consult with the community in the oversight of risk posed by gene technology. Therefore it would seem to be beneficial for the Community Committee to have a public face and to be interacting with the broader community that it is intended to represent. By informing the public about its role as well as the existence of regulation and the way that the public can contribute to it, the Consultative Committee would increase awareness and trust in the regime.

The Community Committee currently has no public communication devices such as a website or electronic forum with which to garner community views. There is sparse information about the committee on the OGTR website and the Community Committee has no email address posted, rather communication to it must be through the OGTR itself. Systems that could foster a more interactive process could be:

- Information on how to contact the Committee, request information or send submissions,
- A separate site within the OGTR server, with a dedicated webmaster,
- An online bulletin board or forum so that community members could post their comments and questions;

- A list of frequently asked questions about the regime (a FAQ);
- Information about gene technology in general or where to find out information about gene technology.

The internet is only one possible communication device. Dietrich and Schibeci have recommended that the Community Committee adopt of 'feeder groups', utilising the advantage of having leaders of key interested constituencies represented on the committee.[31] These groups would collect constituency specific views and information on behalf of the Community Committee. Each Community Committee member would adopt a 'feeder group' and be responsible for communicating with it, attending meetings with it and passing on its findings. However, as Dietrich and Schibeci rightly recognise, such feeder groups would require a degree of funding so as to maintain continued participation and information exchange over the long term. Funding is indeed an important issue. Given that Biotechnology Australia receives more than three times the funding than the whole of the OGTR and that the Community Committee receives a small share of that funding, there is cause to question whether this body could ever achieve the coverage of its 'non-regulatory' cousin.

16.2.2 POLICY PRINCIPLES, GUIDELINES AND CODES OF PRACTICE

The second way that the CSCG proposed that the public would have input to process of regulating was through ongoing consultation on the internal policy mechanisms underpinning the regime. The basis for this policy was explained later by the Interim OGTR as follows:

> [g]iven the high level of community interest in gene technology, it is important that both the Regulator and the Ministerial Council remain "in touch" with community views on issues surrounding the regulation of gene technology. Both the Regulator and Ministers will benefit

[31] Dietrich, H.& Schibeci, R. 'Beyond public perceptions of gene technology: community participation public policy in Australia.' Paper Presented at, *Towards Humane Technologies Conference* (15-17 July, 2002) , University of Queensland, 2002, p 17.

> from the community's input into the [rules] which will underpin the regulatory scheme.[32]

Consultation was envisioned on providing the public with a direct input into the conceptual and practical mechanisms that direct the day to day operations of the OGTR. To reiterate, there are three main sources of internal policy under the Act [see 4.3.1, 6.3.1, 10.3-10.4], which are:

- *Policy Principles.* Subject to altering the legislation itself policy principles provide the most powerful influence on how the Regulator will set standards. They form binding obligations upon how the OGTR operates and what activities are permissible under the regime. As was noted previously, they are statutorily limited to 'ethical issues' or GE free zones, but could be extended to health and environmental matters under the rubric of the Gene Technology Regulations.[33]
- *Policy Guidelines*. Policy guidelines will also guide (but not bind) the day to day operation of the OGTR and the general way the law is applied.
- *Codes of Practice.* These non-binding policies, will standardise various regulatory practices under the Act.

Together these various policy documents a strong influence on the operation of the law and the direction it takes. The CSCG promised that these internal mechanisms would be open to public scrutiny, input and deliberation. Is this the case subsequent to legislative *enactment*?

Policy principles, policy guidelines and codes of practice are the ultimate responsibility of the Ministerial Council, although any committee or the OGTR may advise on the need for and content of such guidelines. The Act only obliges consultation with external bodies in respect of policy principles and codes of practice. Early drafts of the Gene Technology Bill allowed consultation with 'any body considered appropriate', [34] in the drafting of policy guidelines, but this was

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[32] The Interim Office of the Gene Technology Regulator, *Explanatory Guide to the Commonwealth Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra, 2000, p 53.

[33] sub.21(1)(b), 21(3), GTA.

[34] Proposed sub.23(3) *Gene Technology Bill*, December 1999 Draft.

removed entirely, so that there is no mention of consultation in respect of guidelines at all anymore.[35]

The development of policy principles and codes of practice must be undertaken in consultation with the Regulator, all three committees and such industry, environmental, consumer or 'other' groups considered appropriate.[36] Whilst the Act does not specify how such groups will be chosen or if there should be a balance in sectional representation, it is likely that most groups active within the field will be consulted. This is likely because, as a politically based body, the Ministerial Council will be particularly sensitive to the repercussions of excluding an interested party from the consultation process. On the other hand, it must be recognised that there is no obligation to consult with the broader community, that is groups not specified within the legislation.

In early proposals for community involvement the Interim OGTR envisioned that all 'soft law' mechanisms within the Act would be subject to community consultation.[37] This meant that 'policies, standards [and] codes of practice' would be drafted after public notification, calls for submissions and 'comprehensive responses to any submissions made, including details of how the submissions have been addressed'.[38] These proposals were never included in the Gene Technology Bill and the final Act does not require the Ministerial Council to publish a notice or invite submissions, as must be done in respect of some aspects of the risk assessment and management process [see 17.2]. Instead it is largely the OGTR's responsibility to decide who should be involved in rule deliberation, meaning some interested parties may be excluded, as the OGTR was unaware of their presence or simply did not consider them appropriate. Given the impact that these rules have on the standard setting process, I would submit that it is as important if not more important to involve the community at this stage (the

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[35] although the Ministerial Council retains the power to call for advice from either GTTAC or GTCCC, ss.101(d), 107(b), GTA.

[36] ss 22(1)(a)-(g), 24(2)(a)-(g), GTA.

[37] Interim Office Of The Gene Technology Regulator, *Proposed National Regulatory System For Genetically Modified Organisms – How Should It Work?*, Commonwealth of Australia (AGPS), Canberra, 1999. p 37.

[38] *ibid.*

making of law) as it is within the context of the risk governance process itself (doing the law).

16.2.3 COMMUNITY ENGAGEMENT

The final mechanism through which the CSCG envisioned the OGTR undertaking rule deliberation was through, so-called 'direct engagement' of the public though community forums and target consultations.[39] These direct engagement mechanisms were proposed as a response to the Lay Panel's recommendation that 'Government should embrace a commitment to bring together all stakeholders to talk to each other and reach agreement on mutually beneficial solutions … in conjunction with the proposed Gene Technology Office [OGTR]'.[40]

The CSCG declared community engagement activities to be an essential element in a 'documented approach to community consultation and involvement',[41] (read, process legitimacy) allowing a direct interface between the community and the OGTR.[42] Forums would concentrate on 'key issues' in the regulation of gene technology and would be supplemented by targeted consultation with peak industry groups, universities, researchers, consumer groups and peak health and environment groups'.[43] This would allow the day to day operation of the regime to be explained to the public and for the public to explain to the OGTR the impact or perception of that regime on their activities or lives. It would raise awareness of the OGTR and its activities. Although the current discussion concentrates on regulatory communication it is worth pointing out that such forums and consultation would also have allowed a broader discussion about risk between the OGTR and the community.

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[39] Interim Office Of The Gene Technology Regulator, *Proposed National Regulatory System For Genetically Modified Organisms – How Should It Work?*, Commonwealth of Australia (AGPS), Canberra, 1999. p 35.

[40] *First Australian Consensus Conference Gene Technology In The Food Chain*, Lay Panel Report, The Australian Museum, Canberra, 1999, <http://www.austmus.gov.au/pdf/layreport.pdf> (10/10/02), p 6.

[41] *ibid.*

[42] Interim Office Of The Gene Technology Regulator, *Proposed National Regulatory System For Genetically Modified Organisms – How Should It Work?*, Commonwealth of Australia (AGPS), Canberra, 1999. p 35.

[43] *ibid.*

As noted above, public engagement mechanisms were introduced immediately after the Consensus Conference as an indication of the Government's commitment to facilitate discussion of the technology and processes for its oversight within a legal framework. However, the commitment to institutionalising rule deliberation within the GTA regime would diminish with the advent of Biotechnology Australia.

Shift in Communication Role towards Biotechnology Australia. Following the announcement of the National Biotechnology Strategy there was a marked shift in the way the OGTR's community engagement and awareness raising activities were described. In mid 2000, the Interim OGTR made a lengthy submission to the Senate Committee in respect to a number of issues relating to the operation of the (then) proposed OGTR. [44] That document drew heavily on the work of Biotechnology Australia as a source of community attitudes towards the technology and towards regulation.[45] Whilst the Interim OGTR had gleaned information from the consultation process on the Gene Technology Bill, it was clear from these reports that it had begun working with, or at least relying on, information gathered by Biotechnology Australia.[46]

The extent of each body's obligation with respect to engaging the community was explained in September 2000 when the Interim OGTR released its official response to the Lay Panel Report of the Consensus Conference.[47] Biotechnology Australia was to provide 'balanced and factual information on biotechnology [to]

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[44] Interim Office of the Gene Technology Regulator, *Submission to Senate Inquiry*. Department of Health and Aged Care, Canberra, March 2000.

[45] *ibid.* pp 29,33, 40,

[46] The IOGTR states, "According to Biotechnology Australia, the Australian community is being asked to make decisions about the applications of biotechnology without having enough factual and balanced information to help them make informed decisions. They consider that it is important that the community can be assured of: factual information about the technology; the regulation of gene technology; genuine consultation; consumer choice; and consumer benefits. Generally speaking, our research and public consultations indicated that the level of confidence in GMOs and GM products depends greatly on the level of confidence in the responsible regulatory agency and the level of perceived risk of the GMO or product. This was confirmed by attitudinal research undertaken by Biotechnology Australia", *ibid.* p 33.

[47] Interim Office of the Gene Technology Regulator, *How Outcomes Of The First Consensus Conference On Gene Technology In The Food Chain Are Being Addressed*, Interim Office of the Gene Technology Regulator, Canberra, 1999, p 24. .

enhance the public understanding of biotechnology.[48] The OGTR was to be an 'accessible provider of information' that would 'cut across all of the regulatory systems that relate to GMOs'.[49] Thus, at this stage the 'non-regulatory' Biotechnology Australia, would provide general information on gene technology, that is, the science, the purported risks and benefits, whereas the OGTR technologies within its jurisdiction. Hence, there would have seemed to be set roles for each bodies, with the OGTR being accorded a much more specific mandate than its regulatory cousin.

Despite the demarcation of risk communication into general risk discussion (Biotechnology Australia) and specific risk and regulatory discussion, the situation became unclear again with the first report on the National Biotechnology Strategy. In that report the Government sought to clarify the two main roles of Biotechnology Australia's public engagement arm, these being to:

- enhance public understanding of biotechnology and its applications, including the risks and how they are managed; and
- inform the public about the regulatory mechanisms protecting human health, the environment and consumer rights.[50]

By this stage there was an obvious overlap between the role originally envisioned for the OGTR and the role actually adopted by Biotechnology Australia. Both risk and regulatory communication had been subsumed into Biotechnology Australia's portfolio. The minor parties, particularly the Democrats attempted to shift the balance back toward the OGTR, by tabling an amendment which would have required the office to undertake community engagement and awareness raising activities of the regime by the OGTR.[51] These amendments failed to elicit

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[48] *ibid.*

[49] *ibid.*

[50] Commonwealth Biotechnology Council, *Australian Biotechnology : Progress And Achievements - A Companion Document To The National Biotechnology Strategy*, Commonwealth of Australia (AGPS), Canberra, 2002, g 4.

[51] "Certainly a lot of the amendments are designed to ensure that there is that community confidence, and we aim to provide that. The Democrat amendments and the amendments that I have seen from minor parties seek to do that by providing education and public awareness campaigns, as well as by tightening up this regulatory system." Stott- Despoja N, '*Gene Technology Bill* 2000 … In Committee', *Senate Hansard*, 1/12/ 2000. p 20424.

bipartisan support and by the time the OGTR came into operation in 2002, Biotechnology Australia had become the main coordinator of public forums and target studies on both gene technology and the regulatory framework for its oversight.[52]

What can be seen from this development is an immediate – some might even say 'knee-jerk' – reaction to the Consensus Conference and growing crescendo of community concerns over the lack of government led dialogue during the drafting process. The Governmental response was to acquiesce to this demand and include 'documented' mechanisms for participatory governance in the OGTR's portfolio. However, the decision was narrowed in part, by introducing a 'non regulatory' body to deal with 'general information' relating to gene technology. This still left the OGTR with a large portion of responsibility for regulatory communication, particularly in discussing and involving the public in regulatory policy, risk assessment and management. However, over the course of drafting these processes also moved into the 'non regulatory' portfolio of Biotechnology Australia. That organisation continues to operate alongside the OGTR and the Commonwealth's National Biotechnology Strategy remains in place. Just what the impact of this is on the ongoing operation of the OGTR is arguable.

Disadvantages of the Coexistence. The coexistence of these two governmental agencies confuses the role of regulatory communicator. The lack of prescriptive guidelines within the GTA on how the OGTR is to consult with the public compounds this problem. Given the overlap, there is a very real potential that the OGTR and Biotechnology Australia may work cooperatively. It may mean that the OGTR relies on public data gleaned by Biotechnology Australia. Indeed, this has, to a certain extent, already happened [see 17.2.4].

At its first meeting the Community Committee met with the public awareness arm of Biotechnology Australia and agreed to cooperatively develop questionaries aimed at tracking the 'changes in areas of concern, ethical issues, and views of

[52] McCormick C, 'Australian attitudes to GM foods and crops' (2002) *Pesticide Outlook*, 6:**13:**261.

regulatory agencies over the past few years'.[53] Recognising the importance of this committee staying up to date with current public attitudes, there is cause to question whether this association is in the long term interest of the Committee. The OGTR should endeavour to maintain its status as a regulatory agency 'at arms length from industry'.

By operating in conjunction with Biotechnology Australia the impartiality of the OGTR may be called into question. Outsourcing parts of regulatory communication may also draw criticism, because it may once again appear as if the public are being told not to worry because a regulatory system is in place to protect them, rather than entering a dialogue about the best way to cooperatively manage risks. Even if that is not the case there is cause to question whether it is health for the OGTR to place another organisation between itself and its public as the greatest trust is produced through direct not incidental contact with a regulatory agency [see 11.5].

By making community engagement and public awareness a non-regulatory issue, the Government placed much of the process of deliberation and exchange out of the jurisdiction of the OGTR. Whilst the same amount, or indeed more, risk data may be exchanged between government and community in the current system, the result is an effective disengagement of the public from the risk governance process. There will be both an information and regulatory gap between community views and decision making under the GTA. This is a much less involved manner of participation than can be expected from a deliberative risk governance process and was promised by the CSCG during the drafting process.

Advantages of the Coexistence. Above, it was argued that the lack of prescriptive direction within the GTA, coupled with the coexistence of Biotechnology Australia, led to confusion over the exact extent to which the OGTR was to engage with the public. The flip side to this is that the existence of Biotechnology Australia may serve as a welcome refinement of an inherently unclear role. By leaving the responsibility of community engagement, public awareness campaigns

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[53] Gene Technology Community Consultative Committee Meeting, *Communique of 1st and 2nd GTCCC Meeting 17 - 18 April and 15 - 16 July 2002*, Office of the Gene Technology Regulator, Canberra, 2002.

and other general matters to Biotechnology Australia, the OGTR can concentrate all its resources on communicating at the regulatory level alone. The communication process is resource intensive, it will slow or detract from the licensing process. Given the limited resources of the OGTR, the need to undertake a wider public involvement programme may ultimately result in less emphasis on the risk assessment and management process. There is then, cause to argue that Biotechnology Australia takes up a necessary component of the communication process which otherwise would have either overburden the OGTR or have been neglected because of a lack of resources.

Perhaps an even more important reason that the role of community engagement be placed within the jurisdiction of Biotechnology Australia, is to maintain the perception of an impartial regulator. In undertaking a 'public awareness' campaign, there will ultimately be groups that oppose the information, method or approach adopted. The result will be allegations of collusion or bias as has been seen in relation to Biotechnology Australia. It is important for a regulatory agency charged with protecting health and safety to avoid such allegations. It must both be and appear to be objective, concentrating on the risks of individual dealings rather than becoming involved in the broader political questions of whether an industry should be promoted or not.

Hence, there are both positive and negative aspects arising out of the subsuming of the general communication role by Biotechnology Australia. The main concern is that the OGTR will place too much reliance in Biotechnology Australia as its source of public views on how risks should be dealt with. Instead, the placement of general risk communication into the non-regulatory portfolio should facilitate a greater emphasis on regulatory communication and case by case risk communication. Whether this is the case will be discussed below.

16.3 REVIEW PROCESSES

The final way the community can be involved in the scrutiny and review of legislation is participation in formalised legislative review of the Act. This ensures that the community is not estranged from the process of law making

simply because the Act has come into effect. Those who originally deliberated on the form of the legislation can reinvolve themselves after a time period in which the operation of the agency reveals the practical effectiveness or inadequacies of the system. Those who have been affected by the legislation can contribute their knowledge to an affective updating of the law. From the regulatory agencies aspect, review provides a channel by which to communicate to the public, the success or impediments of the regime, and how effectively that agency has operated within it.

The CSCG/Interim OGTR originally proposed for the Ministerial Council to review the Act after five years of operation.[54] The Senate Committee argued that, 'given the fundamental importance of the issues involved, the timeframe, in which the proposed review is to take place, is too long'.[55] It recommended that an independent review be undertaken no more than three years from the commencement of operation of the OGTR.[56]

The three year mandatory review was backed by the Democrats who emphasised:

> [w]e believe this should be a minimum requirement … [as it] is essential to the determination of the most effective regulatory system for genetic technologies in Australia. I acknowledge that the Gene Technology Bill 2000 is not the answer to the wide range of inadequacies in the current regulatory system and that many of the guarantees that the community requires to feel safe about this technology are not provided for by the current regulatory system or that proposed by the Gene Technology Bill and its cognate bills.[57]

The Opposition also agreed with the need to shorten the time period:

> one of the reasons the majority report contains a recommendation for a review after three years and not five is that

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[54] Interim Office of the Gene Technology Regulator, *Explanatory Guide to the Gene Technology Regulations*, Commonwealth of Australia (AGPS), Canberra, 2000, pp.81-2.

[55] *ibid.* para 3.222.

[56] *ibid.*

[57] Stott-Despoja N, '*Gene Technology Bill* 2000 … Second Reading', 7/11/2000, *Senate Hansard*, p 19291.

> we believe this is a very significant area and that it needs to be looked at sooner rather than later to see that what is in place is sufficient to the task or whether indeed it needs even further amendment. I commend those people involved in the discussions who have brought this outcome. It is evidence of the continuing serious commitment by people involved in the GM regulator area to see an optimal outcome.[58]

The consensus was a requirement that the Act would be reviewed no more than four years from the commencement of the OGTR's operation.[59] This provision is now included within the GTA proper, rather than within the Intergovernmental Agreement on Gene Technology, as was originally envisioned by the Interim OGTR. [60] The review must include an examination of the operation of the Act and the 'structure' of the OGTR. Beyond that the Act is silent on what features of the scheme will be reviewed.

The GTA also requires that the review be 'independent'. This means that it must be undertaken by a non-governmental body who is considered to have 'appropriate qualifications' in the area.[61] It would seem that the method, system and manner of the review will be up to the body charged with examining the system, as the Act does not specify these matters. There are no requirements for internal or external bodies, stakeholders or the public to be consulted or included in the review process. The extent to which the Ministerial Council could direct the review body on these matters without impacting on its 'independence' is unclear, as the Act is silent on the matter.

The review provisions within the GTA itself were strengthened with the signing of the Intergovernmental Agreement on Gene Technology. The Agreement obliges the Ministerial Council to undertake an initial review of the 'implementation and effectiveness' of the overall scheme within four years of its

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[58] Crowley R, '*Gene Technology Bill* 2000 … Second Reading', 7/11/2000, p 19296.

[59] sub.194(1), GTA.

[60] Interim Office of the Gene Technology Regulator, *Explanatory Guide to the Gene Technology Regulations*, Commonwealth of Australia (AGPS), Canberra, 2000, pp.81-2.

[61] sub.194(4), GTA.

operation and then every five years following.[62] This review — currently scheduled for July 2005[63] –will be overseen by the Ministerial Council in consultation with the Regulator, all three committees and such consumer, health, environmental and industry groups considered appropriate.[64] Thus. it seems that this will be an additional review to the one specified in the Act, which will be overseen by an 'independent' third party (not the Ministerial Council). Just how the subject of this review and the review within the Act differ is unclear. However, the most important feature of the Intergovernmental Agreement on Gene Technology review is that it requires public involvement.[65] Public submissions will be called for at each review and the Regulator, all three committees (the Technical Committee, the Ethics Committee, the Community Committee) and such scientific, consumer, health, environmental, and industry groups as the Ministerial Council considers appropriate will be consulted on the operation of the scheme.

16.4 CONCLUSION

The virtues of openness, transparency and consultation are recognised in both the structural mechanisms within the GTA and the conceptual and practical frameworks established by the OGTR. Certainly, the OGTR's role in clarifying an extremely complex legislative framework provides evidence of this. Whilst translating the legal technicalities of the Act could certainly be construed as a unidirectional communication strategy, it is an imperative first step to ensuring multi-directional deliberation by all interested parties. It allows non-experts to be informed so that they can enter into a deliberation on, at least near, equal terms.

With Biotechnology Australia taking up a very broad national gene technology communication role, including informing the public about the regime it may be convenient for the OGTR to allow that body to communicate on its behalf. There certainly seems to be an initial acceptance of such a relationship, although this

[62] ss.16(g), GTA, paras, 37,38 Intergovernmental Agreement.

[63] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

[64] *ibid.*

[65] *ibid.*

may change as the OGTR and the Community Committee become more grounded and established. Limited structural mechanisms within the Act that might otherwise guide the deliberation process certainly permit such an outsourcing of public interchange. Notwithstanding the incidental benefits of Biotechnology Australia undertaking such a role, there is cause to question the lasting effect of such a relationship. Some aspects of deliberative risk governance require a proximate relationship between the community and OGTR, so that the community does and is seen to affect the decision making process.

Visible community consultation is achievable under the current system, not least due to a committee that was specifically added to the regime for that purpose. As of yet, the expectations and hopes for the Consultative Committee seem far beyond both its terms of reference and the structural mechanisms provided for its operation. Visible consultation is also achievable with respect to the formation of policies which dictate the day to day operation of the regime. Yet, these too have been 'watered down' from the original model. Under the final framework, the community is no longer an express partner in their design. Rather it is up to the Ministerial Council to pick and choose stakeholders it 'considers appropriate', a notion that rides contrary to the purpose of deliberative risk governance. Such a process recognises that both decision maker and community need to be informed. However, the process set out under the Act assumes that the Ministerial Council will be informed enough to make a decision about who the relevant parties are.

In the absence of any obligation to consult with the greater public there is a very real chance that rather than consult with the greater community, the Ministerial Council will, as obliged, consult instead with the Community Committee, for indeed that body is held out to be the conduit of community concerns. Given its lack of reference, structure and resources, the Community Committee may in turn, choose to source its data from Biotechnology Australia, resulting in a regulatory system that at no stage interacts with the broader community.

The scenario above must be recognised as a rather extreme one, particularly given these bodies are still building the conceptual and practical frameworks that will determine how they interact with their constituencies. Hopefully, the fundamental

guiding principles discussed in the last chapter will ensure a system more akin to deliberative risk governance.

17

DOING LAW : RISK ASSESSMENT PROCESSES AND RISK COMMUNICATION

Whereas the subject matter of the previous chapter fell more within the traditional arena of regulatory communication and theory this chapter moves into risk theory and the conventional notion of risk communication proper. For all the reasons discussed in chapter 12, I would submit that this aspect of deliberative risk governance is of core, if not highest importance.

Unless regulatory review results in a fundamentally different system being put in place, regulatory communication will at best result in a 'tweaking' of the overall framework. Under the *Gene Technology Act* 2000 (Cth) (GTA/the Act), the independence of the Gene Technology Regulator (the Regulator) and the use of risk analysis, means that the risk assessment process will have the greatest influence on the standards applied to GMO dealings. Thus, whilst multi-directional deliberative communication about the form of law is important, it is the actualisation of that law, the internal risk analysis process, where community involvement is imperative.

17.1 THE STRUCTURAL BASIS FOR RISK COMMUNICATION

As has been noted previously, there is no mention of risk communication within the GTA, despite the requirement to undertake risk assessment and risk

management.[1] By not specifically referring to risk communication, the Act seems to subordinate that pillar of the risk analysis paradigm to the other two. Of course, not calling something by its proper name is less important than failing to include it at all. Thus, the real question is if deliberative risk governance is instituted by actual legal mechanisms within the legislation. Risk communication may adequately be dealt with in an inferential manner through various provisions through the Act. Indeed the explanatory memorandum emphasised that the regime would be underpinned by 'effective risk assessment and communication by the Regulator',[2] and the *Intergovernmental Gene Technology Agreement* requires that the Commonwealth ensure the system 'incorporates extensive stakeholder and community involvement'.[3] These constitute, at least a semblance of fundamental guiding principles, advocating the adoption of 'effective risk communication'.

On the other hand, deliberative risk governance is equally about adopting and projecting an attitude which evinces the importance of the community in any discourse on risk. If the Act appears to subjugate risk communication – whether or not it actually does this in practice – then it will place the whole process on the 'back-foot' from the outset. If risk communication is to be truly authentic and honestly participatory it must not only be built into the risk governance process but it must be overtly expressed as part of that process.

17.1.1 CONCEPTUAL AND PRACTICAL FRAMEWORKS

Whilst the Act does not specifically mention risk communication, the Office of the Gene Technology Regulator (OGTR) has incorporated the term and the practice into its risk analysis framework as required by the Intergovernmental

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[1] However, as noted above it is the express function of the Regulator to provide 'information and advice to the Public about the regulation of GMOs' [sub.27(f), GTA]. The breadth of this requirement is not extrapolated upon in the legislation. Nor is the form that information is to be disseminated in explained. This provision seems to relate more to regulatory communication than it does to risk communication. That is, requiring the Regulator provide advice on how to access and use the GTA. However on another interpretation it could be seen to require the OGTR to provide advice on the regulation of previous and present applications for the use of GMOs.

[2] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia (AGPS), Canberra , 1999, p 38.

[3] Recital B.(f), Intergovernmental Agreement.

Agreement [see above]. According to the OGTR 'communication and consultation are key elements of effective risk analysis'. It defines risk communication as the:

> process of ensuring that an open and transparent process of identification of risks associated with ... gene technology and GMOs has been rigorously followed, and; the Community is adequately informed about what these risks are and how they are being managed; and public confidence in the regulatory system is maximized.[4]

As can be noted from Figure 7, risk communication has been integrated into the overall risk analysis structure.

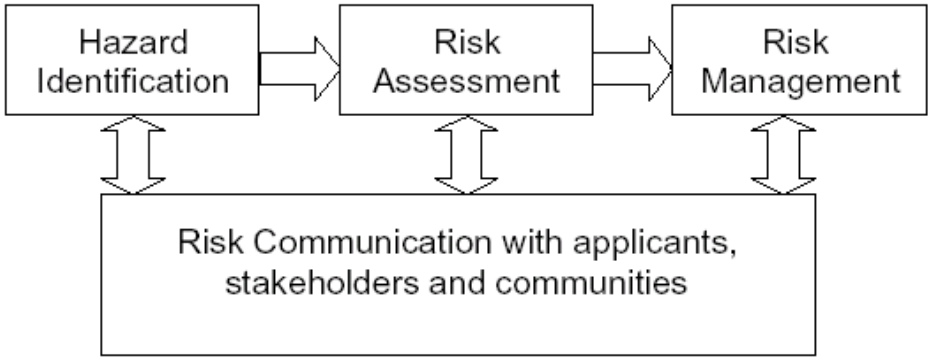

FIGURE 7

This is a policy that reflects a modern approach to risk communication. The following section will examine how the communication approach propounded within the OGTR risk analysis framework is both supported by structural mechanisms within the Act, and how it is applied in practice.

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[4] Office of the Gene Technology Regulator, *Risk Assessment Framework for Licence Applications to the Office of the Gene Technology Regulator*, Commonwealth of Australia, Canberra, 2001, p13.

17.2 COMMUNICATION DURING RISK ASSESSMENT

Much of the assessment process established under the Act is undertaken at an institutional rather than at a regulatory level [see 7.1.5-7.2.2]. Moreover, the licence applicant plays a major role in providing the risk assessment data to the Regulator, as well as participating in designing risk management methodologies [see 7.4]. Whilst the OGTR retains powers to consult any party in respect of the information contained in a licence condition,[5] the applicant will generally be the major source of information relating to the GMO and its risks. This effectively means that the Regulator will always have to rely on the integrity of external information, rather than basing decisions entirely on information from within the agency itself. Certainly, it is hard to argue for a more 'hands on' system. Having a scientific arm attached to the OGTR, responsible for the collection and analysis of risk data, is likely to be cost prohibitive, particularly in a smaller country like Australia. What the outsourcing of risk assessment does oblige, is a much higher level of scrutiny on the risk assessment process, particularly where the proponent of the technology is responsible for the provision of much of the information upon which that assessment is based.

There is then a need to balance out the weight given to the 'perception' of risks from this organisation, by opening up the process to a broad ranging dialogue. External review bodies can be seen to improve such a system through the scrutinisation of the applicants data for flaws and contributing extra risk information which may not have been considered by the applicant organisation.

17.2.1 THE INITIAL CONSULTATION PROCESS

Under the regulatory framework originally proposed by the Commonwealth State Consultative Group on Gene Technology (CSCG) [see 14.1], the OGTR would have been required to 'provide public notification that an application has been

[5] ss.42, 47(e) GTA.

received'.[6] This proposal was taken up in the first draft of the Gene Technology Bill.

Under the first draft, the licensing process required that upon receiving a licence application the OGTR must have published a notice which informed the public of:

- the lodgement of the application;
- the right of anyone to receive further information; and
- a call for submissions from any interested parties.[7]

The Regulator would have been obliged to take any submissions received as part of this process into account in the decision to licence a dealing, and in setting any standards in the risk assessment or risk management plan.[8]

The Final Consultation Requirements. The process set out in the first draft was 'watered down' in succeeding drafts and the final Act. The GTA now only requires the OGTR to undertake the notification process outlined above if she or he considers the proposed dealing may pose 'significant risks to the health and safety of people and the environment'.[9]

Where the Regulator does determine there should be an initial call for submissions, those submissions made must be taken into account in drafting a risk assessment and risk management plan and in the issuance of the license.[10] The Regulator may also consult with anyone deemed relevant or hold an open or closed public hearing on the matter.[11] The OGTR has determined that as a matter of policy the following will be consulted in the risk analysis process:

- the Applicant;

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[6] Interim Office of the Gene Technology Regulator, *Proposed National Regulatory System for Genetically Modified Organisms – How should it work?*, Commonwealth of Australia (AGPS), Canberra, 1999. p 38.

[7] subs. 40(1),40(2)(a)-(c) *Gene Technology Bill* December 1999 Draft.

[8] *ibid*, ss 41(2)(a), 41(3)(a)

[9] s. 49, GTA. If so, the Regulator is required to publish a notice of the application stating that more information can be requested and invite a written submission on whether the licence should be issued [subs. 49(1),49(3), GTA].

[10] subs.51(1)(b), 51(2)(b), 56(2)(c), GTA.

[11] s.53(1)-(3), GTA.

- the Applicant's organisation and its Institutional Biosafety Committee[see 4.5]
- relevant government authorities;
- non governmental bodies affected or likely to be affected by the use;
- organisations licence holder and staff involved with the project; and
- the community.[12]

Whilst the Act requires consultation with the Technical Committee neither the ethics nor community committees need to be consulted [see Appendix 1] and as can be seen from the list above the OGTR has not included the Community Committee in its conceptual risk communication framework. In respect of the ethics committee the OGTR notes:

> Where the Regulator identifies an ethical issue in relation to a dealing which is not covered by a policy principle or by ethical guidelines issued by other organisations (e.g. the National Health and Medical Research Council) the Regulator, may also seek advice on a particular issue from the Gene Technology Ethics Committee.[13]

Consultation from the Outset? In a truly participatory risk communication model, the severity of risk should be determined in consultation with stakeholders. The GTA does not follow this rationale. Rather it requires that the degree of risks be pre-determined by the decision maker before the public or stakeholders become involved. The Regulator justifies this position as follows.

> The general feeling was that it would be very hard for people in the general community – who by and large do not have a lot of expertise to comment on an application – because you only have half the equation. You have the question being posed if you like but the risk assessment plan is the answer. So to ask them to comment at a very early stage is probably very counter-productive.[14]

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[12] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator*, Office of the Gene Technology Regulator, Canberra, 2002, p 24.

[13] *ibid.*

[14] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

This seems to turn the participatory model on its head and undermine the very reason for participatory risk communication. Participatory risk communication is about identifying *all* risks particularly those which a decision maker or risk assessor may be unaware of. It is about coming to an answer together, not deciding on the answer then asking the question.

Even more bewildering is the assertion that the Regulator will turn a matter over to the Ethics Committee where she or he 'identifies an ethical issue'. This presumes that a single agent, who will most likely, not be ethically trained, will be able to identify ethical issues from the outset. Given the complexities of that discipline I would question whether this is also not turning the whole process 'on its head'. One would think it would be the Ethics Committee that would inform the Regulator if indeed there were ethical issues arising out of a dealing.

Proposals to involve the community in every licence application at every stage of the risk analysis process met with reluctance from industry and some sectors of Government. For example, during Gene Technology Bill discussions, the influential Australian Chamber of Commerce and Industry argued:

> [t]he need for rigorous scientific risk assessments is fully supported, however, the consultation process with the public is flawed and may inhibit commercialisation of GMOs. There are several opportunities for the public to make comments, object or ask for further information including at the time of application and after the Regulator has prepared a risk assessment.[15]

The need to streamline the process, not overburden the regulatory system, or inhibit development, are valid concerns which are important in considering the extent of public involvement that will be adopted into a legislative framework. Yet it must be pointed out that the GTA implements a tiered 'bracket' system of regulation [see 6.2]. The licensing system only oversees *new uses* of gene technology in the *open environment*. Applications that replicate existing uses are

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[15] Australian Chamber Of Commerce And Industry, *Regulating Gene Technology*, ACIC Review (April 2000), Canberra, 2000, p 3.

likely to be dealt with in other brackets such as Notifiable Low Risk Dealings (NLRDs) or registered dealings. In those cases there is no obligation for the Regulator to consult with the community. Ensuring community participation on an initial assessment does not seem to be overburdening the system. Indeed, it seems a rather minimalist adoption of a deliberative risk governance model.

The Costs Of Exclusion. Precluding the public from being able to, 'make comments, object or ask for further information' is likely to have a number of costs of its own. These are not only economic but social costs. The price of public dissatisfaction may be higher than that which arises from inhibiting a product from entering the market for a few more days or weeks. Should something go wrong, and the GMO actually cause damage, the fact that the OGTR considered it not to warrant public scrutiny during the approval phase will undoubtedly compound any backlash against the regulatory agency and create a perception of recreancy. Even where nothing goes wrong, the mere fact that the Regulator may consider some new dealings not to warrant public scrutiny may rancour some. Whilst it is recognised that a degree of streamlining is necessary, to say, 'I have consider the evidence not to warrant your consideration' is paternalistic at the least and tendentious at the worst.

In the OGTR Risk Framework, the OGTR has promised that all licence applications will be made available for public comment, in 'most cases' of intentional open release dealings – 'at least initially'.[16] The question is whether the choice to skip the first round of public consultations for open releases should have been left to policy at all. If we are to accept that a participatory model is in any way necessary to identify all risks, legitimise regulatory behaviour and ensure that the public interest is taken into account, then the answer is surely no. The introduction of GMOs into the open environment should always have been subject to a base standard of community and stakeholder review and consultation.

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[16] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator*, Office of the Gene Technology Regulator, Canberra, 2002, p 24.

17.2.2 PUBLICATION OF THE PLAN

Whether or not a plan has been submitted to the public at the first stage of risk assessment, the Regulator is required to publicise the preparation of the risk assessment and risk management plan.[17] This notice must state that further information may be requested (subject to privacy and FOI requirements) and invite written submissions within 30 days in relation to the plans.[18] The Regulator admits that:

> The legislation really anticipated transparency and openness but it is very hard to be transparent in a technically complex area ... people find it hard to get their head around it ... [19]

Whilst there is no obligation within the act to 'translate' either the risk assessment and management plan or the application, the OGTR has promised that:

> [i]nformation on the application will be appropriately presented and accessible, for example, a summary understandable by non-experts will be available, as well as making the full application available for those who are interested[20]

This provided a considerable challenge for the regulatory agency, as it found its feet and attempted to get through a backlog of applications, such that the Regulator admits 'early release documents tended to be "bang" here's a technical assessment'.[21] More recent Risk Assessment and Risk Management Plans in particular have 'tiered' information at various levels, beginning with a simple, lay overview of the application, more complex non-technical information about the parent organism and prodiginy followed by a technical risk assessment. This is intended to:

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[17] by making it available, In the gazette, Newspaper circulating in all states and on the OGTR website. section 52 GTA.

[18] s.52(2) (a)-(d)

[19] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

[20] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator,* Office of the Gene Technology Regulator, Canberra, 2002, 24.

[21] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

> recognise that there are a range of people who will be consulting these documents from real technical experts through to people who have no technical expertise so what we have tried to do is layer the information in [Risk Assessment and Risk Management Plans] more recently.[22]

When the dealings to be authorised by licence do not involve intentional release of a GMO into the environment there is no need to publicise the risk assessment and risk management plan, nor is there any requirement to consult with the public.[23] However the Regulator may consult with a local council or any other person considered appropriate.[24] In the case of Notifiable Low Risk Dealings (NLRDs) there is no need for the Regulator to consult with anyone, including the public. Again however, the Regulator must determine that the dealing would pose 'minimal risk' before it can be determined to be a NLRD.

At any stage during this process any member of the community may request either the application for a licence or the risk assessment and management plan adopted in respect of that license.[25] The Regulator is obliged to provide any information in these documents that is not protected by commercial confidentiality.[26]

Reaching the Widest Possible Audience. In the above discussion it was noted that the Regulator must cause certain aspects of the risk analysis to be 'publicised', so as to allow for public participation in the process. Under the GTA this means that the OGTR must release a notice in, the Gazette (Commonwealth Government Notices Gazette), a newspaper circulating generally in all States (the Australian), and on the OGTR website (www.ogtr.gov.au).[27] Whilst this provides for a *basic* dissemination of information, it is more a passive process than actively seeking relevant stakeholders and interested parties.

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[22] *ibid.*

[23] ss.47,52, GTA.

[24] subs.47(d),47(e), GTA.

[25] s.54, GTA.

[26] *ibid.*

[27] ss. 49(1),52(1) GTA ; Office of the Gene Technology Regulator, *Quarterly Report Of The Gene Technology Regulator, For The Period 1 April To 30 June 2002*, Commonwealth of Australia, Canberra, 2002, p 6.

If risk communication is to be considered as important as the other pillars of the risk analysis paradigm, then it needs to be approached in a systematic and methodological way, not in a passive or *ad hoc* manner. Placing advertisements in newspapers, on website or in email updates, is not a guarantee that all that might be interested in participating in assessing and managing risks will do so. Some groups or individuals will not be regular participants in risk dialogue; they will only become involved where the activity affects them or their business. They are unlikely to be regularly monitoring for OGTR announcements. As one contributor to the Senate Committee argued,

> Many people don't get a chance to read newspapers or read notices of submissions but if the information is brought to people's attention, they will get involved….[28]

17.2.3 NEIGHBOURS

One group of individuals who could reasonably be expected to wish to participate in any deliberation about a proposed activity are the neighbours of any property where a GMO is being used. The law has long recognised the obligations owed to neighbours.[29] Under the common law owners must take reasonable care that substances on their property do not cause damage or nuisance to neighbouring properties.[30] Damage is not limited to physical damage but may involve economic losses, such as access to markets.[31] Nor is the duty limited by distance, so a 'neighbour' could be anywhere within the proximity of the person responsible for

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[28] Submission No.20, p.4 (Ms L McDermott), to the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[29] This doctrine was set out in *Heaven v Pender* which held that, "That case established that, under certain circumstances, one man may owe a duty to another, even though there is no contract between them. If one man is near to another, or is near to the property of another, a duty lies upon him not to do that which may cause a personal injury to that other, or may injure his property " (1883) 11 QBD 503 at 509.

[30] *Oldham v Lawson* [No 1] [1976] VR 654*; Burnie Port Authority v General Jones Pty Ltd* (1994)) 179 CLR 520

[31] *Perre v Apand Pty Ltd* [1999] HCA 36 (12 August 1999), *Dovuro Pty Ltd v Wilkins* [2000] FCA 1902 (21 December 2000).

the GMO. [32] The duty can be heightened where the neighbouring property is particularly susceptible to certain forms of activities.[33] Susceptible neighbours might include an organic farmer, or a conventional farmer growing the same crop type as the modified one. More importantly, owners of property can be under a duty of care to warn others of foreseeable risks upon their property which may cause harm to others.[34]

The duty to protect neighbours is, in part, enshrined in the GTA itself, which seeks to mitigate risks to the overall commons, regardless of location. However, it cannot be denied that the law has traditionally treated proximate neighbours as deserving of a higher duty of care than the ordinary community. The law does not depart from such fundamental principles without some unequivocal intention by the Parliament. As the High Court has reinforced:

> It is in the least degree improbable that the legislature would overthrow fundamental principles, infringe rights, or depart from the general system of law, without expressing its intention with irresistible clearness [35]

To depart from a position where neighbours are considered to need special consideration would be, I submit, a departure from the ordinary course of the law. This is particularly so where the proposed activities could impact on themselves or their livelihoods.

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[32] In *Donoghue v Stevenson* it was made clear that, "I think that this sufficiently states the truth if proximity be not confined to mere physical proximity, but be used, as I think it was intended, to extend to such close and direct relations that the act complained of directly affects a person whom the person alleged to be bound to take care would know would be directly affected by his careless act "[1932] AC 562 at 580-581.

[33] For instance, in *McKinnon Industries Ltd v Walker* [1951] 3 DLR 577, the Plaintiff complained that sulphur dioxide from the D's premises had damaged orchids grown on his premises. The Court granted aninjunction even though that damage exceeded that which would have been suffered by a normally sensitive person in the same circumstances. In *Tutton v Walter* [1986] QB 61 – a defendant needed to stop spraying insecticide when the bees on a neighbouring propery were feeding on flowering crops (on the Defendants property).

[34] *Council of Shire of Wyong v Shirt* (1979) 146 CLR. 40; *Nagle v Rotnest Island Authority* (1993) 177 CLR 423.

[35] *Bropho v Western Australia* (1991) 171 CLR 1, at 17

In recognition of the special status of proximate land owners, the OGTR has expressed its intention to require, as a condition of a license, neighbouring land owners be notified of 'field trials'. What is meant by field trials is uncertain, but it would seem to exclude ordinary licensed dealings. The OGTR does however reiterate there is no positive obligation to notify neighbours within the GTA and has only promised to ensure they are notified 'in most cases'.[36]

The promise, or at least partial promise, to inform neighbours as a licence condition hardly fits within a deliberative risk governance process. This is *ex post facto* communication, that is, the decision will have already been made to allow the use of the organism before the neighbour is informed. As noted above, even the common law expects that in some instances one land owner will refrain from 'ordinary' activities where their neighbour may have a particular sensitivity to it. The best way of ensuring that sensitive neighbours are not affected by activities within a licensing context, is to allow these neighbours to contribute to the risk assessment process. Through early stage risk communication these parties can best identify their own susceptibility to risks posed by the dealing, so a licence can be tailored to suit. Hence, I would submit there should be a positive obligation to identify susceptible neighbours and allow them to contribute to the risk assessment of any GMO released into the environment.

Using A Risk Communication Plan. One way of ensuring that all parties – and in particular neighbours – potentially affected by a proposed dealing are included in the risk analysis process would be to undertake a risk communication plan as part of or parallel to the hazard identification processes. Risk communication plans are encouraged under the Australian model for risk communication, as set down by the National Health Partnership (NHP) *Guidelines for Assessing Human Health Risks from Environmental Hazards* [see 12.2]. Such a strategy would consider from the outset:

- How to best identify 'anybody who may perceive themselves to be affected', by the dealing or its downstream uses, understanding that *all* groups may not be identified;

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[36] Office of the Gene Technology Regulator, *Handbook to Gene Technology in Australia*, Commonwealth of Australia (AGPS), Canberra, 2002, Ch 7 pt D.

- What likely groups will wish to be involved, so that information or materials can be tailored to these audiences,
- How to best contact identified groups,
- How to facilitate participation of these groups within the decision making process.

It is these individual 'one off' interested parties who must be actively sought out in a concerted planned manner. Just as there is a need to institutionalise risk assessment and risk management there is perhaps cause for the establishment of a 'risk communication' plan or 'risk communication strategy'. Perhaps the best body to undertake such a risk communication plan would be the Community Committee. That body's role is discussed below.

17.2.4 THE COMMUNITY COMMITTEE'S ROLE IN RISK COMMUNICATION.

The Gene Technology Community Consultative Committee (the Community Committee) was developed in response to calls for a mechanism within the GTA regime that would bring together stakeholders, community members and the decision-maker, to find 'mutually beneficial solutions' in the governance of risk [see 15.2]. During Gene Technology Bill debates both the Opposition and Minor parties argued that Community Committee should take up a role of communicating about the risks of gene technology with the broader community.[37]

As a representative body with a direct line of communication to the OGTR and Regulator the Community Committee is well placed to serve as a conduit for the interchange of risk information between the OGTR and the community. With respect to communication *into* the OGTR it could garner public opinion on applications under the Act or in respect of classes of activities. With respect to communication *out of* the organisation it is well placed to translate risk information to specific 'feeder groups' [see 16.2.1].

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[37] For the oppositions position on the role of the Community Committee see Forshaw M, '*Gene Technology Bill* 2000 … In Committee', 7/12/2000, *Senate Hansard*, p 21219.

Because the Act is so non-descript about the role or function of the Community Committee there are two possible ways that the Committee might have undertaken risk communication with the public. These are:

- communication about the general risks posed by gene technology ; and/or
- risk communication about specific licence dealings.

As will be seen below, neither of these potential roles really eventuated in practice.

Risk Communication About Gene Technology in General. The Community Committee has met with Biotechnology Australia twice in its first triennium. On both these occasions it has been Biotechnology Australia who informed the Community Committee of the trends in public attitudes towards gene technology, not the other way around. However, the Community Committee has agreed to 'participate in the development of the next questionnaire that will contribute to this ongoing research'.[38] Evidently it is Biotechnology Australia who will undertake public engagement and interaction and not members of the Consultative Committee.

I will not repeat my arguments about the problems associated with cooperation between the Committee, as a part of the regulatory agency and its non-regulatory cousin [see 14.3.2, 15.2, 16.2.1]. However what this agreement does indicate is an acceptance by the Community Committees that it is not to undertake independent broad scale risk communication. This is borne out in practice with the Committee not conducting any independent engagement work thus far. Nor is there a great deal of recorded communication between the Regulator/OGTR and the Community Committee about the risks posed by gene technology. Rather the majority of inter-departmental communication seems to be about the process of regulating and how it might be made more transparent or accessible.[39] That said it

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[38] Gene Technology Community Consultative Committee Meeting, *Communique of 1st and 2nd GTCCC Meeting 17 - 18 April and 15 - 16 July 2002,* Office of the Gene Technology Regulator, Canberra, 2002.

[39] See variously, Gene Technology Community Consultative Committee Meeting, *Communique 4th GTCCC Meeting 20th Feburary 2003,* Office of the Gene Technology Regulator, Canberra, 2003 ; Gene Technology Community Consultative Committee Meeting, *Communique of 5th GTCCC Meeting 5 June 2003,* Office of the Gene Technology Regulator, Canberra, 2003 ; Gene Technology Community Consultative Committee

has set two priorities which may facilitate better general risk communication in the future.

Two working groups have been established within the Community Committee to consider:

- issues associated with public understanding of science, risk and public perceptions of gene technology; and
- processes by which the OGTR can improve community consultation and participation including review of the effectiveness of information and communication provided to the community in general and to the regions involved in limited and controlled releases.[40]

This form of communication between the Committee and the Regulator would seem, at the moment at least to qualify as process or regulatory communication [see 16.2, 18-18.1]. That is, it revolves around communicating about the process of governing risk rather than communicating about risk itself. However, the exact outcome of the working group findings is not yet clear and there is always the potential that such work will be directed to the improvement of risk communication generally.

Codes of Practice. One area of general risk communication guaranteed under the act is the requirement for the Community Committee to be consulted on policy principles and codes of practice.[41] I discussed these principles as part of the process of regulatory communication above, because they form part of the legal framework and are prospective only [see 10.4]. However, in some respects, discussion that occurs between the Committee and the OGTR about such principles qualifies as what would be conventionally described as general risk communication. This is because it allows the Committee to impart its broader social and community of risk to the regulatory agency in response to policy and

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Meeting, *Communique of 7th GTCCC Meeting 29 April 2004*, Office of the Gene Technology Regulator, Canberra, 2004.

[40] Gene Technology Community Consultative Committee Meeting, *Communique of 5th GTCCC Meeting 5 June 2003.*

[41] subs.22(1)(c) and 24(2)(c), GTA.

guidelines proposals put to it by the OGTR (which will be drafted in respect of the OGTR's view of risk). The following example highlights this point.

In December 2003, the Community Committee was presented with an amendment to a policy principle outlining State moratoria rights. The proposed amendment was as follows:

> The designated area may only be recognised by the Regulator where one or more states have produced peer reviewed scientific data, after taking into consideration proposed licence conditions, buffer zones, demonstrating that the GM event will move by sexual or asexual means to a level beyond the acceptable threshold for adventitious presence into GM or non-GM crops for that area's major market.
>
> The Regulator may only recognise the designated area where the GM event (DNA) is present in the commercial product used in human food manufacture.
>
> Licence conditions that flow from the recognition of this policy principle shall be reviewed annually taking into consideration new scientific data and market threshold requirements.[42]

Through this alteration, we see an attempt by the OGTR to restrict policy principles – originally intended to ensure the system took into account more than physically quantifiable risks – to scientific grounds only. The adoption of such an amendment would have shifted the focus of these policy principles from economic and jurisdictional grounds to human health and safety alone. It would have restricted the scope of GM free zones to food crops only, not pharmaceutical, bioremedial or other crop types. It would have also severely circumscribed state's ability to declare moratoria on other economic grounds, such as upstream segregation or local organic, or overseas market standards for buffer zones that were not the area's major market. The restricted interpretation would also seem to preclude the declaration of a whole state as GM free because each crop would have to have been tested on a case by case basis, within specific vicinities.

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[42] *ibid.*

Consequently the Committee voted against the amendment of the policy principle.[43]

The ability to consider policy principles such as the one above fulfils some of the expectations of and promises for the Community Committee during drafting [see 3.6, 14.5, 15.2]. Through consultation on these principles the regulatory agency can communicate, consider and deliberate with the OGTR about the use of 'non-GMO alternatives' and the 'political, cultural, [and] financial … ramifications' of such a choice [see 3.6]. [44] It also ensures – as was clear from the above proposal – that regulatory decisions, 'take into account more than just science. [45]

Risk Communication about Individual Dealings. The second risk communication role that the Community Committee might have taken up is as a proxy between the Regulator and community in respect of individual licence applications. Originally the Government did not consider that the Community Committee should play a role in assessing applications at all. After some lobbying by the Opposition and minor parties,[46] a consensus was reached which saw the Community Committee providing advice on individual applications where requested by the OGTR or Ministerial Council.[47] It was also agreed that a member of the Community Committee would be placed on the Technical Committee, as this committee was privy to each licence application.[48]

As an advisory body only, the Committee cannot intercede between the Regulator and the public unless it is specifically requested to do so. This situation is similar

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[43] *ibid.*

[44] 10th March 1999; The Australian Museum, *Lay Panel Report*, Australian Consensus Conference on Gene Technology in The Food Chain (12/3/1999), The Australian Museum 1999. p9.

[45] *ibid.*

[46] *ibid.*

[47] s.107(aa), GTA; amended after Senate debate see, Interim Office of the Gene Technology Regulator, *Quarterly Report*, Commonwealth of Australia (AGPS), Canberra, 2000, p 12.

[48] s.7(a), GTA, amended after senate debate, see. Forshaw M, '*Gene Technology Bill* 2000 … In Committee', 7/12/2000, *Senate Hansard*, p 21219. Despite the addition of a Consultative Committee member, the original requirement for a lay member of the Technical Committee was not removed from the Act. Hence, the Technical Committee is now required to have at least two community members. However, the fact that the Consultative Committee is constituted from stakeholders rather than laypersons is most likely cause enough to retain the lay role on the Technical Committee.

to the process of consultation in respect of Risk Assessment & Risk Management Plans discussed above [see 17.2]. Just as the community will be involved only when it is considered necessary, so too will the Community Committee be only be consulted with at the discretion of the Regulator. In the vast majority of cases the Committee's general role will be to examine the communication process in an *ex post facto* manner, rather than *actually* being involved throughout the process of risk analysis. The one exception to this rule has revealed that the Community Committees role will be minimal even where it is invited to comment in advance.

The Canola RARMP. The Community Committee has only been asked on one occasion thus far for input into the Risk Assessment and Risk Management process in respect of the commercial release of GM Canola.[49] After reviewing the applications and discussion the matter the Committee resolved to advise the Regulator that :

> [t]he [Community Committee] expresses concern that a state of community unreadiness [sic]exists concerning the risks to the environment of the commercial release of GM canola, so significant that the applications should be declined at this time. [50]

Two committee members (the chairmen of the Australian Landcare Council and Valley Seeds/Access Genetics Pty. Ltd.) dissented to this resolution.[51] They argued that, *inter alia*, the Committee 'was not technically qualified to review the risks to the environment posed by or as a result of the commercial release of GM canola' and that any risks should be reviewed solely by the Technical Committee. Apparently, the view that the evaluation of risk is the domain of risk experts alone, exists even within the Community Committee itself.

The attitude that the review of Risk Assessment and Risk Management is the domain of technical and scientific experts only, seems to have been confirmed in the way that GM canola was approved by the Regulator. The submission of the

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[49] DIR 020/2002; DIR 021/2002 <http://www.ogtr.gov.au> (11/10/04)

[50] Gene Technology Community Consultative Committee Meeting, *Communique 4th GTCCC Meeting 20th Feburary 2003*, Office of the Gene Technology Regulator, Canberra, 2003.

[51] *ibid.*

Community Committee was not mentioned once in any documentation relating to the decision to permit the dealing. In particular the lengthy *Risk Assessment and Risk Management Plan* which contains a list of responses by the OGTR to feedback on the application is strangely silent on the Committee's one attempt to involve itself in the risk analysis process.[52]

Whilst the Regulator had promised internally to take into account the Committee's submission,[53] there is neither a public record that the submission was actually considered in the making of the decision to licence the dealing nor a statement of reasons as to why it was deemed inappropriate or irrelevant. Failing to recognise the Committee's submission publicly not only calls into question the transparency of the system, it greatly undermines the importance of that body – intended to be a representative of the public interest – within the overall regime.

The Community Committee's assessment of the 'unreadiness' of the Australian community to accept a GM food crop was clear in the number of submissions made on these dealings from the general community. In excess of 250 responses were received by the OGTR the majority of which opposed the grant of a licence on social, consumer, ethical, economic, trade or precautionary grounds. Only economic or trade grounds were responded to at all within the Risk Assessment and Risk Management Plan. The plan states:

> [f]eedback from extensive stakeholder consultation during the development of the *Gene Technology Act* 2000 made it clear that the community wanted the regulatory system to focus exclusively on the evaluation of risks to human health and safety and the environment.

Note that the OGTR does not state that the community wanted ethical, social or community risks, issues or concerns – call them what you will – taken into account. Rather history seems to have been rewritten somewhat, so that the 'substantial community concerns surrounding the introduction of [gene

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[52] This is true in respect to all subsequent Canola releases: DIR 020/2002; DIR 021/2002; DIR 032/2002 <http://www.ogtr.gov.au> (11/10/04).

[53] *ibid.*

technology] into the market'[54] – as recognised by the government at the time of drafting [see 3.10.1]– now seem to have only pertained *exclusively* to human health and the environment.

The statement that the community was exclusively concerned with physical risks seems to ride against the *Explanatory Guide to the Gene Technology Bill*, which justified the Government's grounds for legislating gene technology. In that document, under the heading 'What are the possible risks of the technology?' the Government recognised that 'broader, non-scientific concerns … have been expressed about the use of the technology including ethical, social and moral concerns'.[55] This recognition that the community was not exclusively concerned with scientific risks and that the regime should these broader concerns into account was not an anomaly. The House of Representatives stated that the system should 'acknowledge the value that consumers place on environmental, economic, ethical and social considerations, and address them'.[56] The Interim OGTR itself stated during drafting that:

> the need for moral and ethical issues raised by gene technology to be considered and factored into the regulatory system, is very important, and must be addressed.[57]

It assured the community that:

> as proposed by the Lay Panel Report, the new regulatory system will be based on an objective scientific assessment of risks but will take into account many factors including, but not limited to … Community views … [and] Ethical issues.

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[54] *ibid.*

[55] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra. E-version:
<http://scaleplus.law.gov.au/html/ems/0/2000/0/0642438692.htm>

[56] House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* Report (February 1992), Commonwealth of Australia (AGPS), Canberra 1992. Paras, 3.21 & 3.45

[57] Interim Office of the Gene Technology Regulator *How outcomes of the First Concensus Conference on Gene Technology in the Food Chain are Being Addressed.* Information Bulletin No.4 September, AGPS, Commonwealth of Australia 2000. p 20. .

Yet, two years on, the non-scientific, social, ethical and moral concerns seem to have vanished from the agenda and the risk governance process is *exclusively* concerned with scientific, human health and environmental considerations – because, according to the OGTR, that's what the community apparently demanded.

In respect of the canola licence applications, community views on human health and safety and the environment *were* responded to and economic objections were rejected with a generic *statement of reasons* (the grounds highlighted above). However, other social, ethical or moral community objections were simply *disregarded* as 'OSA' – Outside the Scope of the Assessment. In other words, the only community concerns that will be taken into account in respect of individual dealings are ones that relate to physical, scientifically assessable hazards. The social ethical, moral legal objections will be ignored, as apparently were the Community Committee's recommendations.

Given the fact that the 'significant' 'unreadiness' of the Australian community was an insufficient basis to 'accept the worst-case scenario' and waylay commercial release of GM canola for the short term, the states saw it fit to take matters into their own hands. All states in Australia with the exception of Queensland, where the climate is not suitable for the GM variety to grow, declared moratoriums of varying degrees on GM canola. Whilst these moratoria were declared on the basis of trade and segregation issues, this was the only way that the states could constitutionally prohibit the use of the technology under the national regime. Whether or not trade issues were the sole grounds underlying the decision to ban GM canola in the short term, the Australia-wide ban does seem to indicate a national 'unreadiness' in line with the Community Committees submission. It seems unfortunate that it is state legislatures that have acted on significant community concern whereas the OGTR deemed it inappropriate.

How then does the community express its concern about a specific dealing if the OGTR excludes all 'broader non-scientific concerns' from the risk assessment process? Obviously it is not through the Community Committee because apparently they do not have the 'expertise' to become involved in risk assessment

or risk management. Nor is there any apparent way of directly lobbying that committee to pass on such objections to the Regulator. Yet, because there is no 'ethical assessment' or 'social assessment' [see 8.3-8.4] recognised within the GTA there is no mechanism within the risk analysis process through which non-scientific objections can be voiced, taken into account or respond to. The only clear way thus far would be to go outside of the system and lobby state legislatures to declare GE-free zones on trade grounds. The promise that the system will 'take into account many factors', particularly 'non-scientific' ones, appears not to apply to individual dealings at all. Such a system does not place 'non-physical' risks *on par* with physical ones [see my argument at 8.4], it seems to ignore them altogether.

If the community really is in a state of 'unreadiness' about individual dealings they appear to only be able to oppose such dealings on scientific grounds. This appears to be inviting the community to 'cry wolf' [see 8.2] and couch their objection in scientific terms regardless of whether that is the actual basis of concern, because otherwise they will be ignored. Moreover, if the Community Committee – who actually have a degree of expertise in gene technology – have been deemed both internally and by the agency not to be 'technically qualified' to comment on risks to human health and the environment, then it follows that the community proper isn't really qualified to comment on such risks either. Whilst at least there is a statutory requirement to take into account the broader community's objections (unlike the committee that represents it) such an attitude seems to indicate that its concerns won't be taken very seriously.

Clarifying the Committee's Role. The Community Committee has thus far not taken on a very involved risk communication role within the regime. In part, this is a consequence of the lack of prescriptive direction within the GTA as to the Committee's functions and mandate. Yet this lack of prescription could be seen as positive because it allows the Committee to adopt a more proactive level of involvement in risk assessment and management in the future. This would, of course, require a shift in attitude within the OGTR and even within the Committee itself. Clarifying the role of the Committee might also be considered in the upcoming review of the regime in 2005.

One possible role for the Committee within the risk analysis process could potentially be in determining which bodies should be communicated with prior, during and after risk assessment. Indeed, the Community Committee may have been a much better arbitrator of whether the first round of consultations should be open to the public for comment than the Regulator, as a single agent, can be [see 17.2.1]. Given that the body represents a broad spectrum of sectional interests it is unlikely that it would be too proactive in determining such matters. Rather, it would provide a capable and balanced assessment of whether it was in the public interest to consult from the outset of the risk assessment process.

The recognised need for a concerted, planned approach to identifying and structuring risk communication was highlighted above. The Community Committee is particularly suited to conducting such a plan. At its first meeting the Community Committee made informing neighbours a priority issue. It has resolved to examine ways of communicating with neighbours.[58] The effect of this investigation is forthcoming, but it would not seem too onerous a task to send written notice to landowners in a vicinity where an application has been lodged. Indeed, the involvement of neighbours is probably a minimalist approach. Other parties that could also be considered to warrant a formal notification of the lodgement of an application could include:

- parties with an equitable interest in the land, for instance lessors, graziers, indigenous landowners;
- any body involved in downstream uses of the organism;
- handlers such as grain elevators;
- food manufacturers using the organism;
- local communities; and
- local government.

Methods adopted to encourage these bodies to become more involved in the risk governance process should go beyond passive communication. That may require using government resources such as the ABC's print news, radio and television as well as written correspondence with various members of the community.

[58] *ibid.* .

Members of the Community Committee are also in an ideal position to involve the interests of various community sectors as the very reason for their appointment is that they represent stakeholder interest.

17.3 OPTING OUT AND ACCEPTING THE WORST-CASE SCENARIO

In chapter 12 when the concept of risk communication was expounded, it was argued that the success of the process was partially reliant on adopting the right attitude. That is, the decision maker should approach risk communication realising that it may not always turn the community around to her or his way of thinking. The decision reached after a deliberation may seem hard to understand, at least from the 'experts' standpoint, but if that decision is not respected, the whole process may suffer as trust in the system is diminished. Given the Government's position is currently in support of the development of gene technology [see 3.14], then the 'worst case scenario' is that, despite the existence of comprehensive risk legislation and effective risk governance, the community may decide it will not accept GMOs whatsoever.

Principle 7(d). As noted above, the Consultative Group on Gene Technology undertook an initial round of consultations in lieu of the drafting of the Gene Technology Bill. The result was a series of principles, which were to guide the development of the new legislative framework. Among these principles was principle 7(d) which stated,

> If a participating jurisdiction considers that the release of a GMO or a GMO product will pose an unacceptable risk within its territory, then it may decline to allow release within its own territory or impose additional conditions on release within its own territory.[59]

[59] Draft discussion paper for consultation: Interim Office of the Gene Technology Regulator, *Proposed National Regulatory System for Genetically Modified Organisms – How should it work?* Commonwealth of Australia (AGPS), Canberra, 1999.

This provision was included to allow any jurisdiction to prohibit the use of a GMO or apply more stringent conditions on the release of a GMO on 'health, environment or trade/economic' grounds.[60]

However, by the release of the more comprehensive framework for the Gene Technology Bill [see 14.1], principle 7(d) had been omitted. It was later revealed that the CSCG had decided that the policy was contrary to a centralist, independent and authoritative regime and that there were sufficient mechanisms for the consideration of regional issues in the decision making process.[61]

The decision to abandon principle 7(d) met with derision from the Tasmanian Government which berated the Government for disallowing 'State flexibility to make it's own decisions on GMOs'.[62] In other words, the Federal Government would be the final arbitrator of what was acceptable or unacceptable in a state.[63]

The Federal Government argued that Tasmania's position was untenable, on both constitutional and international law grounds.[64] Subsequently, there was no provision for States to 'opt out' or declare GM free zones within the Gene Technology Bill tabled for debate in Parliament.

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[60] Senate Committee Sub. No.77, p.155 (IOGTR); to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[61] *ibid.*

[62] Submission No. 89 (Tas Govt) p 11, to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[63] Indeed, the Federal Government did later admit it would not accept a position which allowed States to have a 'veto role' over a Federal Regulator. "The government will be opposing these amendments. These amendments fundamentally alter the operation of the national scheme. They also give local governments a veto role over the scheme. Therefore, these amendments are strongly opposed. As it currently stands, the bill ensures that there is full consultation across all state and territory governments, local governments and the community for every proposed release of a GMO into the environment." Note, that at the time of this speech, the Government had actually agreed to a watered down version of the opt out provisions which would fall under policy principles. However Senator Brown of the Greens continued to lobby for full opt out rights. Tambling G, '*Gene Technology Bill* 2000, Gene Technology (Consequential Amendments) Bill 2000, Gene Technology (Licence Charges) Bill 2000 In Committee', *Senate Hansard*, 1/12/ 2000, p 20434.

[64] Citing advice from the department of foreign affairs and trade. Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000, para 6.39.

The Tasmanian Government continued to lobby for the rights of States to create GE free zones. Without the existence of institutional mechanisms which ensured that States were given a genuine voice in deliberations Tasmania refused to sign the Intergovernmental Agreement on Gene Technology, arguing:

> [a]n opt-out clause is imperative for a cooperative national regime. The Tasmanian Government has decided that, in the absence of an opt-out clause, Tasmania will not sign the InterGovernmental [sic] Agreement (IGA) that is to form the basis of the nationally consistent regime. It is considered that, should Tasmania sign the IGA, our options for controlling GMOs in our State become unacceptably limited.[65]

Other States also began to consider their rights to limit or prohibit the use of GMOs within their jurisdiction. In Victoria, the incumbent Bracks Government promised to investigate the possibility of creating GE free zones as part of its election strategy.[66] In Western Australia, a bill was introduced into Parliament to place a moratorium on GMOs and the State Government promised to lobby for GE free zones as part of the CSCG.[67] The Federal Government, while still maintaining a complete opt out would be impossible, agreed to consider alternative mechanisms for allowing states to have a more effective say in state matters. The Minister for Health Care suggested that one solution might be to permit the Ministerial Council to issue codes of practice protecting the positions of various regions.[68]

The Senate Committee considered both State and Federal arguments, concluding that only the High Court could ultimately decide the validity of a state opt out. The Committee argued that in the absence of an *actual* opt out provision the Commonwealth 'should *effectively* provide an opt-out' [emphasis added], in line

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[65] Submission No. 89 (Tas Govt) p 11, to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[66] Submission No.115, p.2 (Victorian Government, Mr Steve Bracks, Premier), to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[67] Macdonald K, 'Warning On `Frankenstein Milk' As Farmers Reject Ban', *Sunday Times*, 02/4/2000, p 11.

[68] Submission No. 89 (Tas Govt) p 11, to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

with the recommendation of the Minister for Health Care.[69] It therefore recommended that 'the Regulator to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions be strengthened'.[70] This recommendation was taken up in the Senate by the Opposition (all State Governments were Labour, which was in Opposition at the Federal level, at the time) and was finally agreed to by the Government.[71] The new provision allows the Ministerial Council to issue policy principles 'recognising areas, if any, designated under State law for the purpose of preserving the identity of … GM crops [or] non-GM crops, for marketing purposes;'.[72]

The addition of this provision to the GTA placated concerned States, ensured the Intergovernmental Agreement was signed and thereby guaranteed a nationally consistent and comprehensive regime. Initial resistance aside, the incorporation of this provision amounts to an institutional recognition that certain regions have the right to have their opinions heard in respect of activities which occur within their own jurisdiction. It evinces a willingness on behalf of the Federal Governments to accept a 'worst case scenario'. Interestingly the provision has been used to over-ride the OGTR where it has *not* accepted a worst case scenario. As noted above. the States have used this provision to respond to substantial community concern, by declaring moratoria on GM canola after the OGTR approved it for commercial release against advice from the Community Committee and predominantly negative community feedback on the Risk Assessment and Risk Management Plan [see 17.2.4]. Just how long such moratoria can or will stay in place is questionable, but it is evident from their acceptance within a policy principle,[73]

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[69] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000, para 6.87.

[70] *ibid* 6.88.

[71] "This amendment is the result of a lot of hard work by the Labor Party to try to bring about a position whereby the rights of Tasmania and other states to declare GM-zones within their state's boundaries are recognised in this legislation. This was not something that the government wanted to accept at the outset but, through the good work of the Labor Party, we have managed to reach a position whereby this amendment recognises areas designated under state law as GM-free zones for marketing purposes."; Forshaw M, '*Gene Technology Bill* 2000 …', *Senate Hansard*, 4/10/2000, p 20485.

[72] sub. 21(1)(a), GTA.

[73] Gene Technology (Recognition of Designated Areas) Principle 2003 (Cth) Commonwealth of Australia Special Gazette No. 340, 5 September 2003.

that the States have retained a degree of autonomy under the regime. This can only be seen as beneficial to the long term stability of a nationally consistent framework.

17.4 CONCLUSION

There was some discussion at the beginning of this chapter about the significance of risk communication not being included as an express part of the risk analysis process within the Act. In that discussion it was posited that, while it was not the most favourable system, failing to describe something did not mean that it didn't exist. Rather the real test would be whether it was sufficiently dealt with by institutional mechanisms within the GTA and by the conceptual and practical frameworks adopted by the OGTR.

As discussed above there are several positive aspects of the risk communication process adopted in both the GTA and the practical framework adopted by the OGTR. The GTA ensures that all relevant information must be disclosed to those requesting it. It requires that the community must be at least notified of the creation of risk assessment and risk communication plans, and in some instances the lodgement of an application. Despite initial reluctance by the Federal Government, the GTA makes provision for individual jurisdictions to refuse to allow GMOs within their vicinity whatsoever.

On top of these institutional mechanisms the OGTR has endeavoured to ensure that risk information is translated into accessible language. This is extremely important to guaranteeing all interested parties can involve themselves, regardless of their level of expertise. The OGTR has created a risk analysis framework, which expressly includes the process of risk communication. The diagram reproduced in this chapter from that framework shows an integrated system of risk communication with applicants stakeholders and 'communities'. This conceptual framework would seem to enshrine the 'ideal' deliberative risk governance process. It recognises that there are diverse 'communities', it requires multi directional communication at each stage of the risk analysis process and most importantly it is underpinned by institutional mechanisms within the GTA.

However, scrutiny of the practical application of this framework reveals that diagrams can often be somewhat misleading.

What the OGTR's risk analysis diagram doesn't show is that consultation at 'every stage' of the process will only occur at the discretion of the decision-maker. Nor is it clear that when it refers to 'communities', it means those communities who actively monitor the OGTR website, the Commonwealth Gazette, or the public notices section of a national newspaper on the odd chance there may be a call for submissions on a GMO dealing which in some way interests them. This cannot be said to be a proactive system and with respect to certain sensitive parties, such as neighbouring farmers, organic or otherwise, it cannot be said to be an effective system.

The lack of proactive mechanisms that ensure that all interested parties can be involved in risk governance is not irrevocable. It can be overcome by instituting practical frameworks such as risk communication plans and by using the institutional resource of the Community Committee. Yet this committee does not seem to have taken up or been given a very active role in risk communication, especially in relation to individual dealings. In the one case where the Community Committee has attempted to comment on a Risk Assessment and Risk Management plan it has been largely ignored. This appears to be on the grounds that a body that represents community concerns it is not qualified to comment on risks. What message does this convey to the community as a whole? This is not to say the Community Committees role will not develop into a more proactive and involved one. The committee has struggled to understand its mandate and role within the OGTR and much of its work over the past two years has been in providing itself with a clear agenda. Certain functions identified by the Committee which relate to risk communication have been under review and may change its focus in the future, especially following the review of the Act in 2005. Whether this occurs is yet to be seen, but it must be reiterated that the lack of guidance and support for that body within both legislation, governmental policy and regulatory practice has severely proscribed what had the potential to be a very powerful risk communication tool.

What is perhaps revealed in the contrast between the conceptual and practical framework is an overall reluctance within the whole GTA system to truly commit to absolute community involvement. It certainly capacitates the processes, it provides the mechanisms to ensure risk communication, community consultation and deliberation but allows for such processes to be applied at the discretion of the decision maker. Perhaps underlying the regime is the philosophy that the public will eventually tire of the subject and no longer wish to be involved. The regime certainly allows for risk communication to be wound back if that event ever occurs.

18

ENFORCING LAW: COMMUNICATING ABOUT THE REGULATORY PROCESS

The final element of deliberative risk governance relates to the enforcement of the law. This does not necessarily mean the community must involve themselves in policing behaviour, (although it does not preclude it either). It does, however, require communication *about* regulatory behaviour. It obliges an interchange on whether 'the form of the law is being adequately applied, whether the processes for risk governance are working in practice and whether the regulator is truly acting in the public interest' [see 12.4]. I have termed this pillar of deliberative risk governance 'process communication'.

Process communication is more akin to traditional administrative notions of transparency and accountability. It involves sharing information about what has been done rather than what will be done (as is the case with, *making* and *doing* law above). This ensures that the community is kept abreast of regulatory behaviour and can be assured that the Agency is acting in the public interest. Process communication will also contribute towards public trust in the regime, so long of course, as it is clear that risks are being dealt with adequately.

Process communication feeds back into the other components of deliberative risk governance. It is important to learn from mistakes and continue the development of both the regulatory framework and the conceptual and practical frameworks for

its day-to-day operation. Information relating to what standards have been set, how they been applied in practice and how successful they were in fostering information flows are all relevant to regulatory and risk communication.

18.1 PROVIDING INFORMATION

The following discussion will examine the mechanisms within the *Gene Technology Act* 2000 (Cth) (GTA/the Act) for communication about the effectiveness of regulatory processes. This will be considered in two parts, the first of which is how information is disseminated by the Office of the Gene Technology Regulator (OGTR) about regulatory activity (providing information), the second being how information is communicated back to the office (receiving information).

18.1.1 GMO RECORD

Under the Act, the OGTR is required to keep a 'comprehensive' record of all dealings, uses and products relating to genetically modified organisms (GMOs) in Australia (entitled 'the Record)'.[1] The record is a public document, which must be made available to anyone upon request.[2] The Act specifies that it may be kept in electronic form,[3] which has meant that the Record is now available on the OGTR website.[4]

Information on the Record will include GMOs which fall under other regimes, such as foods, therapeutic goods or agricultural and veterinary chemicals.[5] Where licensed under the GTA, the information relating to the licence, such as the name

[1] S.138, GTA.

[2] S.139, GTA.

[3] Sub.138(7), GTA.

[4] <http://www.ogtr.gov.au/gmorec/index.htm> (24/1/03).

[5] Sub.138(5), GTA. This information must include: the organisation responsible for the GM product; a description of the GM product with respect to the responsible regulatory regime which covers it; the type of product it is; the scientific and common name of the parent organism; the introduced trait; the identity of the introduced gene; the date of the decision to allow the product into Australia; any conditions attaching to the use of the GM product.

of the holder and the conditions of the licence must be recorded.[6] In the case of Notifiable Low Risk Dealings (NLRDs), the name of the licensee and the type of NLRD must be specified.[7] Registered dealings must describe the GMO, its uses and any conditions imposed by the OGTR.[8]

All states are required to notify the OGTR of any decisions made at a local level which relate to GM products and the OGTR must place such notices on the register.[9] The OGTR must also ensure that all information it receives relating to GMOs or GM products is placed upon the Record 'as soon as reasonably practicable'.[10]

An Important Risk Communication Device. The OGTR describes the Record as 'an important element of the risk communication process'.[11] Indeed, the Record marks a major departure from the secrecy afforded to technology by both industry and government pre-implementation [see 13.1-13.3]. The Record is evidence of an attitudinal shift towards process legitimacy by instituting actual mechanisms for the dissemination of information the community has expressed a desire to know. In a way, it tempers the complexity of having a multi-agency regulatory system, by providing a centralised information resource on all GMOs, regardless of their final use. It creates a more transparent appearance and allows the public to keep up to date with the status of regulation in Australia. Thus, the Regulator states:

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[6] Sch 4, prt.1.para.1.1.1 Regulations. In relation to licensed dealings, the following information must be recorded: the name of the licensee ; all persons covered by the licence the persons covered by the licence; all dealings authorised by the licence; all licence conditions; the parent organisms scientific and common names; the type of traits introduced; the date of issuance and expiry.

[7] The name of the organisation proposing to undertake the notified dealing; the kind of notifiable low risk dealing proposed (different kinds of NLRD are referred to in the Schedule 3, Part 1, Regulations); the identifying name given to the proposed undertaking by the organisation; the date of the notification s.39, Regulations.

[8] S.77, GTA. Information relating to registered dealings must include, a description of any dealings on the GMO Register, a description of GMOs covered by the dealing and any conditions which cover the use of the GMO.

[9] Para.7.(c) Intergovernmental Agreement.

[10] Sub.138(8), GTA.

[11] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator*, Office of the Gene Technology Regulator, Canberra, 2002, p 13.

> the thinking behind [the Record] was that if the gene technology legislation wasn't going to over-ride everybody else then there had to be a central place where anybody could look and find out what was going on with gene technology in Australia. Therefore that record is a very important interface for people who want to consult on what's been approved and what's in process.[12]

An Incomplete Record. There are several pieces of information, which could be considered quite important to deliberative risk governance, that are not contained in the record. These are:

- *The final risk assessment and risk management plan.* Whilst the OGTR makes available an initial risk assessment and risk management plan for public comment, any changes to this plan are not required to be recorded in the Record.[13] The risk assessment and management plan remain the most comprehensive risk data source for any individual dealing. It would seem imperative that the final document be recorded for further use. Indeed this has been the practice of the OGTR thus far, despite the lack of any positive obligation to do so under the Act.[14]
- *Information collected as a condition of the licence*. This should be included on the Record, thus ensuring that the process of risk governance is a shared responsibility. This information is extremely important in 'feeding back' into both regulatory and risk communication processes.
- *Licence refusals.* Information about refusals is another important aspect of process communication. The reasons behind why an application was considered too high a risk or unacceptable are relevant for three reasons. First, it provides evidence that the OGTR is willing to disallow activities where there is good cause, and thus is acting in the public interest. Second, because it avoids unnecessary duplication and allows risk profiles to be

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[12] *Public Lecture: Gene Technology Regulator, University of Tasmania, 14/1/05.*

[13] However, they may be specifically requested at any time by a member of the public and the OGTR must provide a copy [sub 58(1)(b), GTA].

[14] See for example DIR 033/2002, DIR 032/2002, DIR 031/2002 OGTR website <http://ogtr.gov.au> (3/1/03).

established which can be used in future risk communication and decision making. Finally, because it allows future applicants to examine the past refusals, to evaluate the likelihood of their own applications succeeding.

- *Variations, suspensions or cancellations of a licence*. This information is important for the same reasons outlined with respect to licence refusals, and also because it provides an indication on how a licensee has behaved in the past, which may impact on future applications.

Further Improvements to the Record. The GTA sets out the basic structural mechanism of the Record, specifying the type of information which must be entered onto the Record and the basic procedures to ensure it gets there. However, it does not specify how that Record is to be constituted, the way the information is to be presented, or the manner in which it will be organised. Evidently, these are the 'conceptual and practical' frameworks which must remain flexible so they can be improved and updated to capacitate changes in technology and policy. They are, however, extremely important to the success of the Record in effectively reaching the intended audience. The existence of the Record is only one component in institutional legitimacy; the real test is whether the information on that record is sufficiently tailored to its audience, is accessible and able to be effectively incorporated into the risk communication process.

The current online Record is extremely hard to use. It is not stored in a database form, hence dealings cannot be searched for by location, organism type or organisation type. Rather it is a series of pages with listings of PDF and RTF documents. This makes the documents quite large, and further requires proprietary software to access (something prohibited in many public libraries). On each dealing page are so called 'summary documents', which list the relevant organisation, the common and scientific name of the parent organism, the modified trait and the licence date details. These refer to an extended RTF document by reference number (for instance 'See Word Document entitled DIR010/2001)'. The term 'summary' is misleading because none of the information contained in the 'summary' document (organisation, common & scientific name etc) is actually found in the extended document. Should a user bypass the 'summary document' and browse the site by location or dealing type,

they may spend a great deal of frustrated time (as this author did), attempting to find the organism type, the trait type or the organisation conducting the dealing.

Risk assessment and management plans are stored on another area of the web-site. These contain the vast majority of risk data and information on the organism and the conditions under which it will be used. Documents are not electronically linked, rather the user must navigate through the website to find the relevant document by number. To see where the dealing is taking place requires going back to the dealing page and finding the right document map (also referred to by DIR number).

In all, the current record system is a confusing web of information which must be checked and cross checked. It is far from simple to understand, particularly for the lay person and requires some tenacity to use. This is not a transparent system, at least to a large proportion of the population. Rather it is a system for experts, or experienced users.

The OGTR has noted that it is working with IT specialists to develop a more effective and comprehensive version of the Record (entitled the Gene Technology Information Management System), which 'should also make it easier to search for information'.[15] Hopefully this new system will make the Record more 'user friendly', particularly for the lay person or casual user. The only problem is that, while the framework is being established to make the system more 'user friendly', the application process continues.

Submissions to the OGTR have already complained of the rapid pace of the approval process, which, it is claimed has made 'responding in great detail difficult'.[16] Having to spend so much time and effort interpreting the Record will invariably compound this problem for those who wish to stay informed. Interested parties should not have to 'struggle' to stay involved. An optimal

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[15] <http://www.ogtr.gov.au/gmorec/recordinfo.htm> (12/11/02).

[16] Submissions 12,13; Office of the Gene Technology Regulator, *Risk Assessment And Risk Management Plan, 'Application For Licence For Dealings Involving An Intentional Release Into The Environment, Agronomic Assessment Of Transgenic Sugarcane Engineered With Reporter Genes, BSES'*, DIR 019/2002, Office of the Gene Technology Regulator, Canberra, December 2002, p 66.

deliberative risk governance model capacitates, and even encourages, community participation by providing information in a form relevant to its audience. It does not 'allow' participation, so long as the audience is willing to raise its knowledge and expertise to a level suitable to understand the data provided.

18.1.2 REPORTING

Reporting on the operation of the scheme is fundamental to process legitimacy. It means that the process of regulating is transparent, that the regulatory agency accounts for the powers vested in it and that risks are being sufficiently attenuated. The Gene Technology Bill, as originally tabled, required the OGTR to produce an annual report on its activities, and allowed for the Regulator to table a report to Parliament where she or he saw fit. There was no specification within the Bill about the content of those reports or the activities which had to be reported.

The original reporting provisions were considered inappropriate both by the House and Senate Inquiries [see 14.4]. The House Inquiry recommended that the OGTR should provide quarterly reports for the first three years of operations. This call was taken up by the Senate committee, which further recommended that the reporting provisions be more specific and outline basic information which necessarily should be included in the report.[17] This included 'relevant information on the functions and operations of the Regulator including facilities licensed and breaches of licence conditions'. As a result the Bill was amended and the Act now requires that the Regulator report quarterly to the Minister and this report be tabled in Parliament.[18]

The quarterly report must include information on all GMO licenses issued, any breaches of existing licenses and all auditing and monitoring of dealings by the Regulator during the quarter. The original annual reporting requirement has been maintained and remains particularly vague on the information that is to be included, stating that the report should include 'operations of the Regulator during

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[17] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000, paras, 3.165-3.166.

[18] ss 136(1) , 136(3) , GTA.

that year'.[19] Like the quarterly report the annual report must be tabled before Parliament. Unlike the quarterly report the Act additionally requires the States receive a copy of the annual report.[20]

18.1.3 CONFIDENTIAL COMMERCIAL INFORMATION

Whilst the law now views GMOs as 'products', they do not fit the traditional definition of 'goods', inasmuch as they are physically indistinguishable from their non GM counterparts, are self replicating and are only usually valuable en masse. Their real value lies in the intellectual property used to create and maintain them. The protection of this intellectual property is pivotal to the competitiveness of gene technology companies, particularly local start-up ventures. The need to protect such information may derive from several factors, including but not limited to:

- market competition and corporate espionage;
- the inability to obtain sufficient R&D investment necessary to obtain patent rights without successful field trials (in the interim the only method of IP protection may be to maintain trade secrets); and
- incidental information relating to the crop which may, if released have an effect on the organisations relationship with other companies, its share price or market performance.

If it is to be accepted that a regulatory system imputes a conditional acceptance of certain activities then it must act to protect both the interests of the community and the licensee. All international and domestic risk communication guidelines recognise that complete unfettered information exchange must be offset by the rights of private interests [see 12.1]. However, protection of trade secrets must be considered in light of the potential for estranging the public from the risk communication process and creating distrust in the regulatory system. Opponents of commercial confidentiality argue that it diminishes the transparency of the

[19] sub. 136(1), GTA.

[20] s. 136(3), GTA.

regime and is a 'mechanism to prevent legitimate public inquiry into matters that may, or have, harmed the public or the environment'.[21]

There is an invariable tension between the public interest of open unfettered access to information, including risk information, and the public interest in protecting property rights and ensuring the competitiveness of industry. The challenge in the regulatory sense is to facilitate and balance both interests, in a way which ensures community and stakeholder trust and participation.

CCI Provisions Within the GTA. The Act provides for a person to make an application for any information, used in the regulatory process, to be declared confidential commercial information (CCI).[22] The Regulator is empowered to make such a declaration she or he determines the information to be:

- a trade secret;
- having a commercial value which may be diminished by publication;
- is protected by legal privilege;
- could unreasonably affect the person, organisation or undertaking.[23]

Just what constitutes 'unreasonable effect' to the person, organisation or undertaking is rather vague and would seem to only be narrowed by a common sense approach. Equally vague is the limitation on declaring information CCI if the Regulator considers that the prejudice of release would be outweighed by the public's interest in disclosure.[24] How the Regulator is to determine what is in the 'public interest' is not set out within the Act. This will be a subjective and somewhat unpredictable determination. Perhaps a more trustworthy way of determining the public interest would have been to involve the Community Committee in reviewing such information.

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[21] Submissions No.82, p.7 (Environs Kimberley), No.35, p.9 (GE-Free Tasmania), No.69, p.2 (Friends of the Earth (Perth, WA Group)) to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[22] s.184, GTA.

[23] sub.185(1), GTA.

[24] sub.185(2), GTA.

The Act does not make it clear how an application for CCI affects the risk analysis process. This is especially problematic where the application is refused. In such a circumstance the information remains to be treated as confidential until appeal rights are exhausted. It could be expected that the risk analysis process should cease during the appeal period, but there is no guarantee of this. If the risk analysis process continues while an appeal is ongoing, much of the information exchanged would be subject to CCI, regardless of whether it was later determined CCI provisions were inapplicable. Conversely, should the applicant withdraw from the licensing process due to a refusal to declare information CCI, there is no obligation for the OGTR to keep that information secret. This could forseeably occur if a company is attempting to release a product internationally but wishes information about it to be withheld from its competitors anywhere in the world. It may be more valuable not to release the product in Australia and keep information about it confidential in the rest of the world than to release it here and disclose trade secrets.

18.1.4 FIELD TRIAL SECRECY

A matter of particular concern to the industry during debates over the GTA was the release of information relating to the location of field trials. Their concern followed several well publicized cases of GMO crop destruction by activists in the UK. AvCare lobbied particularly hard to have trial locations protected. They argued that secrecy was necessary to protect both the rights of the GM producer and the farmer from 'wanton and premeditated property damage' and vilification from anti-GM) activists.[25] They further argued field trial secrecy would inhibit GM material being removed from a site location.[26] Several other independent companies made submissions to the Senate inquiry arguing for the need to keep GMO trials secret because of vandalism, notwithstanding that no such behaviour had ever occurred in Australia.[27]

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[25] Submission No.32, p.7 (Avcare Ltd) to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[26] *ibid.*

[27] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000, paras 3.132 – 3.134.

Opposition To Secrecy Provisions. Opponents of field trial secrecy argued that it would place those potentially affected by a licence at a disadvantage as they would have no way of knowing that a trial was occurring in their vicinity.[28] They argued that the location of GMOs was an important risk factor, which the public had the right to know about. Local councils were particularly concerned that they would be 'kept in the dark' about trials being undertaken within their jurisdiction.[29] Certainly, the secrecy afforded to trials by GMAC [see 13.3.1-13.3.3] served to heighten concerns over secrecy. The Senate Inquiry agreed, recommending that instead of field trial secrecy, severe penalties for vandalism should be enacted.[30]

The Government's response was to combine both these recommendations so that the Regulator was able to declare the location of 'field trials' CCI and that such sites are simultaneously protected from vandalism by criminal penalties.[31] To quell misgivings about the declaration of trial sites as CCI, the GTA now requires that the Regulator be satisfied that 'significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed'.[32] The Regulator is further required to make a public statement of all reasons for the decision.[33]

The Meaning of Field Trial. The term 'field trials' is unclear. There is no definition in the Act which would assist the determination of when a crop ceased being a trial. Moreover, the onerous provisions relating to withholding 'field trial' locations would not seem to apply to ordinary commercial uses of GMOs. Thus, a commercial crop location could be declared CCI without the need for the Regulator to disclose reasons for the secrecy.

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[28] *ibid,* para 3.130.

[29] *ibid.*

[30] *ibid,* 3.144.

[31] subs. 185(2A), 192A, GTA.

[32] s.185(2A), GTA.

[33] including why the Regulator was not satisfied the Public interest outweighed the prejudice caused by a disclosure, and why there was potential for significant damage to the health and safety of people, the environment or property[s.185(3A), GTA.]

The Effect Of CCI Provisions. Once the declaration has been made, CCI cannot be published as part of:

- the community consultation process;[34]
- in risk assessment and risk management plans; [35]
- as part of a NLRD record;[36]
- on the register of GMO & GMO product dealings;[37] or
- in any document made public by the regulator[38].

Nor can the information be used by the Regulator in considering other GMO licensing applications (without the express consent of the owner).[39] CCI information is also precluded from FOI requests.[40]

Under the Intergovernmental Agreement [see 15.1.2], the OGTR must enable access for States and Territories to all confidential information.[41] This relates to any information in connection with applications, notifications and licences, and monitoring, inspections and enforcement under the Scheme. Electronic access will be provided to publicly available information and, where appropriate security arrangements permit, to confidential information.

The effects of the CCI provisions under the GTA are quite broad and, if declared, affect the vast majority of information that would ordinarily be exchanged with the public. Likewise, the provisions for the protection of 'trial sites', whatever that phrase means, have also raised concerns about industry protectionism.

Double Jeopardy? The Commonwealth Office of Regulation Review's *Guide to Regulation*, states that:

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[34] s.54(2)(a), GTA.

[35] s.54(2)(a), GTA.

[36] s.138(4), GTA.

[37] s.138(3), GTA.

[38] ss.54, 138(3)-(5), GTA.

[39] sub.45(c), GTA. This stops one applicant utilizing the information of an earlier applicant to minimize the resources dedicated to licence application.

[40] s.38/Sched 3, *Freedom of Information Act* 1982(Cth).

[41] An extremely important provision following the Tasmanian debacle involving the refusal by GMAC to disclose the existence of field trials to the State Government [see 14.3.2].

> [s]ecrecy provisions in legislation are to be no broader than is required for the purposes for which they are enacted, particularly bearing in mind the policy underlying the *Freedom of Information Act 1982*.[42]

Given the GTA establishes severe penalties for the destruction of GM crop sites, it is questionable whether a separate secrecy requirement is necessary to protect the same crops. Whilst entrenching both deterrent and secrecy doubles the protection afforded to innovations it also tips the legislative balance against transparency.

How might the CCI provisions have been tempered to foster greater transparency? One way would be to describe the nature of the information protected by a CCI provision and the reasons the Regulator has chosen to keep it a secret. The Regulator is only required to explain why information has been withheld if it relates to the location of a field trial. [43] In other cases no reasons must be provided nor would the nature of the information withheld be recorded.

Obviously the need to justify the declaration of information as CCI may undermine the secrecy of that information. However, an important distinction must be made between the *nature* and the *content* of CCI. Whilst the content of such information may be justifiably withheld, it may be important to allow the community to access data on the percentage of information which falls under various categories. For instance the nature of the CCI information may relate to health matters. On the other hand, it could pertain to company ownership. The latter could be considered less relevant to transparent risk analysis than the former. Allowing access to the nature of information declared CCI might mitigate concerns that potentially hazardous products are being hidden from the public. As Gibbs argues 'if there is no public record of the type of information being withheld, then the public record, *in toto*, is valueless.'[44]

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[42] Office of Regulation Review, *A Guide to Regulation,* 2nd Ed, Commonwealth of Australia, Canberra, 1998, para 6.27.

[43] sub.185(3A), GTA.

[44] Submission No.70, pp.2-3 (Professor A Gibbs); to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

The Community Committee's Role In CCI Determination. Currently only the Regulator oversees the CCI process, no committee nor the Ministerial Council is involved. A further way of ensuring public scrutiny would be to allow the Community Committee to review or participate in the CCI approval process. Of course the Community Committee members would need to be bound by confidentiality requirements. Nor need they actually involve themselves in the decision itself with the exception perhaps of providing advice to the Regulator. The mere review or scrutiny of the Community Committee would go some way to involving the community, if only slightly, in all aspects of the risk governance process. It would foster trust that the mechanisms necessary for the protection of commercial information were tempered by mechanisms for oversight review and scrutiny of the information itself.

18.2 RECEIVING INFORMATION

As the OGTR notes, monitoring and review is necessary to ensure:

> that the risk management approach adopted is effective and to enable ongoing evaluation of the impacts of the GMO on the environment, and the health and safety of people … This enables any changes in circumstances to be assessed in terms of altering risk priorities, and ensures that the management plan remains relevant [45]

An ideal deliberative risk governance process is one in which monitoring is undertaken on a continued basis, by all interested parties, in an interactive way, with a view to building more comprehensive risk profiles and better informing continuing risk governance. The OGTR recognizes this, stating:

> [m]onitoring enables the evaluation of whether or not predictions from a previous risk assessment were accurate and whether or not the risk management measures are adequately managing risks and ensure that the licence holder is complying with the licence conditions. Monitoring and review may also provide important information for the subsequent risk assessment of the same or related GMOs.[46]

Under the GTA, the only agents external to the OGTR proper, specifically recognized as having a role in monitoring and reporting of breaches, are those covered by a license. However, the OGTR has declared that it will investigate information from:

- self reporting by the relevant organisation;
- auditing a report provided by an organisation;
- a report made by a member of the public; and

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[45] Office of the Gene Technology Regulator, *Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator*, Office of the Gene Technology Regulator, Canberra, 2002,p 26.

[46] *ibid.*

- a monitoring visit conducted by the Regulator or staff of the Regulator.[47]

18.2.1 MONITORING & REPORTING

As a condition of any license, the licensee must inform the Regulator of any:

- additional risk information relating to the GMO;
- contraventions of the licence whether they are intentional or unintended; and
- unintended side effects of the dealing,[48]

This is a positive obligation and the licensee is assumed to have known of the existence of the new information, regardless of whether they recklessly overlooked it.[ε]

Whistleblower Provisions. The Act also 'permits' other persons, covered by a license, to inform the Regulator if they become aware of any new risk information or unintended side effects of the dealing.[49] The person vesting such information is expressly protected from civil liability arising from the damages caused to the licensee or any other person because of the provision of information to the Regulator.[50] This is an extremely important 'whistleblower' measure, which ensures that parties privy to confidential information or trade secrets are protected against being sued by their employer or any other party who may be damaged by the release of the information to the Regulator. It is, however, limited, inasmuch as the Act does not oblige the Regulator to act upon the information, but the OGTR has indicated that this will be the case.[51] If a person submits information in good faith, and the Regulator does not act on that information, the next most obvious option would be to report to other bodies, such as the Ministerial Council,

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[47] Office of the Gene Technology Regulator, *Handbook to Gene Technology in Australia,* Commonwealth of Australia (AGPS), Canberra, 2002, p 60.

[48] sub.65(1), GTA.

[ε] sub.65(2), GTA.

[49] That is, a third person covered by the licence 'may' inform the regulator [s.66, GTA.]

[50] s.67, GTA.

[51] The OGTR has promised that: "The OGTR appreciates notification of any potential breaches. All calls will be taken seriously and all allegations will be investigate", Office of the Gene Technology Regulator, *OGTR Monitoring And Compliance Activities,* Fact-sheet, Commonwealth of Australia, Canberra, 2002, p 1.

other government agencies or the media. The Act does not extend whistleblower protection for such reporting.

Private Reporting. Sections 66 and 67 of the Act, which provide for persons covered by a licence to report risks arising out of the licensed dealing were originally intended to cover 'any person'. In the Explanatory Memorandum to the Gene Technology Bill the Interim OGTR indicated that the provisions were meant to cover any 'person who becomes aware of any contraventions of the licence by a person covered by the licence, or becomes aware of any unintended effects'.[52] However, the final Act only covered licence holders, not general members of the community. There is now no direct provision within the Act that encourages or protects public reporting on licensed activities. Despite this apparent oversight, the OGTR's policy is to encourage public involvement .[53]

The OGTR encourages members of the public to report possible breaches of the legislation by fax, email or letter to the OGTR.[54] The OGTR website provides both online reporting forms and downloadable documents to register possible breaches. The complainant is informed that:

> If you think someone you know is not complying with their responsibilities under the *Gene Technology Act 2000*, we want to hear from you. We depend on good information to deal with people who are breaking Australia's gene technology laws and to ensure industry integrity.

The complainant is further assured that all information received will be 'treated in the strictest confidence'.[55]

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[52] Interim Office of the Gene Technology Regulator, *Explanatory Memorandum to the Gene Technology Bill 2000*, Commonwealth of Australia, Canberra. p 62.

[53] Interview with Sue Meek, Gene Technology Regulator (14/1/05).

[54] Office of Regulation Review, *A Guide to Regulation*, 2nd Ed, Commonwealth of Australia, Canberra, 1998, p 60.

[55] Office of the Gene Technology Regulator, *Allegations Of Non-Compliance Form*, Commonwealth of Australia, Canberra, 2002. p1.

18.3 CONCLUSION

Process communication is perhaps the most well established and institutionalised part of the deliberative risk governance process. No doubt this has been facilitated by the acceptance of the principles of accountability, transparency and freedom of information into modern administrative law. It was argued above, however, that process communication requires extending these established principles so that they accord with deliberative risk governance. Such an approach has been ensured by institutional mechanisms within the Act. The extension of the conventional administrative law principles has also been extended by the construction of practical frameworks by the OGTR to ensure community reporting is ensured and protected.

Perhaps the most contentious element of process communication involves those provisions relating to the protection of commercially confidential information. The CCI provisions which have been placed in the Act are very much a creature of earlier failures in risk communication strategy and indeed the 'war on error'. The need for secrecy was due, in part, to the vandalism of GM crops elsewhere. Such vandalism caused the industry to distrust what the public might do to with information. The result was that they argued that the public should not be privy to trial site locations whatsoever. Paradoxically, such vandalism was due,[56] in part, to anger about the secrecy originally afforded to such crops and a distrust of those who had not consulted the community about their release [see 3.2]. Furthermore, the great emphasis that various stakeholders and the public placed on minimizing the breadth of CCI arose from a distrust in regulatory agencies to act in the public interest. Such distrust was a direct consequence of GMAC's failure to adequately involve local communities in the risk governance process whatsoever.

The conflicting interests behind the current CCI provisions are indicative of the tensions faced in deliberative risk governance generally. Whilst the various international risk regimes promulgate free and open dialogue about risks, they concurrently recognize that unfettered access to information will have commercial impacts.

[56] Elsewhere, there were no cited cases in Australia.

The challenge in the design of risk regulation is to balance the public interest of disclosure with the public benefits that derive from protecting commercial interests. Achieving this balance will invariably offend some and cause distrust in others. The question will be how much distrust is to be tolerated and the effect that such a perception will have on the regime as a whole. Too few mechanisms for the protection of private information will ostracize industry and make regulating it harder. Too many mechanisms will create, at the very least, the appearance of a unidirectional risk communication system and undermine public trust in the regime. I would reiterate that a most effective balancing device might be the Community Committee, although this does not yet seem to have been realised in practice.

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CONCLUSION

Gene technology promises great advances in primary production, agriculture and the environment for an agrarian economy like Australia. In the foreseeable future, it may also benefit mainstream society, with improvements in living standards, synthetics, food quality, medicines and therapies. Yet, despite these promised improvements, many people continue to fear the impact of gene technology will have on their lives. Such fears stem from a variety of concerns, from the notion that genetic engineering amounts to 'playing god', to concerns that it may actually harm existing farming practices, so valuable in our agrarian economy [chapter 2].

Because gene technology is the most recent in a series of technological advancements, this thesis has documented a public wariness of its promises and a high level of concern about potential risks it poses can be sufficiently attenuated by those in charge of it. The rise of this blame society has placed increasing pressure on the Government to enact legislation that can control and direct novel technologies in the public interest [chapter 5]. However, the archaic devices afforded by the law have made the task of reigning in the technology a challenging task for legislators. The challenge has resulted in law-makers breaking with legislative convention and instituting new regulatory mechanisms better able to match the indefatigable advancement of the modern age. Thus, we have seen a counter-revolution in law making and the rise of modern risk governance, a system of regulation that is both standardised and plastic. The *Gene Technology Act* 2000 (Cth) (GTA/the Act) is an example of this trend [chapter 4].

The modern risk governance process achieves flexibility by using a combination of soft law and risk analysis procedures [chapter 6]. If it did not do this it would quickly be rendered irrelevant. Its effectiveness is reliant upon scientists and technologists who can interpret and explain technology – otherwise the potential for informed and meaningful decisions would be stymied. Risk managers require technical experts to assess the probability of physical risks arising from technology so as to delimit parameters in which to make decisions. Both the assessment and management process must be set out in a documented, technical form to permit objective review and scrutiny. This thesis demonstrated how risk governance has rendered the regulatory process a technical, scientifically oriented and dynamic system – a system not unlike the technology it controls.

I have argued that this form of risk governance is the most suitable for the task of regulating novel technologies such as gene technology [chapter 7]. However, like any other legal, technical or political system its benefits must be considered alongside its pitfalls. By adopting risk analysis as a regulatory device, the distinction between the law and its subject matter can become blurred. It is hard to engender trust in such a system because it appears that the regulatory regime is intrinsically linked with what it regulates. The immediate solution to the perception of regulatory bias has been to make the decision-maker 'independent' from everyone, so as to legitimise the process. Doing this betrays the assumption that both the scientific and regulatory disciplines can be objective and value neutral – they cannot. This is not an indictment on these systems, but a recognition that as soon as people become involved in the equation and the equation involves interpretation or discretion the outcome will be subjective and value laden [chapter 9].

Perhaps the only way to render the decisions truly value neutral would be to allow a computer to make them – taking the fusion of law and technology to an absolute and absurd extreme. Whilst certainly the modern risk analysis paradigm can no longer be said to advocate such absolutes, there remains an underlying dichotomy between 'science' and 'everything else' – a structure which tends to lead to the decision making process being oriented towards one discipline, often to the detriment of others [chapter 8]. Of itself, this is not necessarily a bad thing. I have

maintained that the best way of truly evaluating the risks of any activity is to separate out the sub-components of risk and allow them to be methodologically considered under their various disciplines. Indeed, my overall argument is that the risk analysis process is the most suitable approach to modern risk governance. This does not mean we must accept this process with all its faults. We should identify and remedy such faults, particularly where they would weaken or undermine the legal and democratic principles we have conventionally considered imperative.

Risk analysis obliges a methodological, systematic approach to assessing technical, physical and quantifiable risks (risk assessment), but has not, traditionally, required the same degree of scrutiny of 'everything else'. (risk management). This has made risk analysis 'top heavy', oriented and dominated by technocrats, whose view of risk is narrower than that of the general public. They tend to see unquantifiable, ethical or social concerns as obfuscating. Such attitudes can creep into risk management and infuse the whole of risk governance. As such, the very bodies who risk governance regulation was intended to control appear to be in control of risk governance [chapters 5, 7, 8]. The result is that the risk governance process can be less than democratic because it is more a relationship between scientists and regulator, rather than between the regulator and public. As such, there is a need for institutional mechanisms that ensure the broader social construct of risk is properly represented. Justice Kirby argued that, for this to occur, technological regulation would have to begin creating a 'dialogue between scientists and the community and scientists and lawmakers'.[1]

The development of risk communication (as part of the risk analysis paradigm) proves the foresight of Justice Kirby. Like gene technology, risk communication was not much more than a vague notion at the time Justice Kirby issued his call for legal reform. Over the past two decades risk communication has been increasingly looked to as the nexus between scientists, community and lawmakers in a 'desperate struggle' for the salvation of the risk governance process [chapter 11]. That struggle has spurred the continued evolution of risk communication so

[1] Kirby M, *Reform the Law*, Oxford University Press, Melbourne, 1983, p 238.

that it has become a broader concept, intended to be more inclusive and more integrated into risk assessment and risk management.

Gene technology has been one of the most significant catalysts in the maturation of the risk communication process [chapter 13]. The perceived impacts of that technology pervaded the public psyche and heightened the public disenfranchisement with how and by whom the technology was being controlled. The community proved that they would not allow democracy to become a 'myth and shibboleth',[2] insisting that the promises of the risk communication *concept* be guaranteed in risk governance *practice*. Such calls have been caught up in a movement to make the whole risk governance process more participatory and integrative – not just risk assessment or risk management, but the very law that supports it. The result is a confluence of the democratic principles expounded in the disciplines of administrative, regulatory, and risk theory. I have termed this more unified approach to public participation in the law making process deliberative risk governance [chapter 12].

The GTA is very much part of the movement domestically and internationally towards deliberative risk governance. It was enacted so as to countermand the perceived disempowerment of the public and public institutions by gene technology and to reinvolve the public in decisions relating to its introduction and use [chapters 13, 14]. Accordingly, the GTA is a very public statement that the Government is willing to take control of gene technology on behalf of the Australian community and – once that has been done – ensure that community has a part in controlling it for the benefit of society as a whole.

The GTA places Australia at the forefront of the international move towards a more democratic system of risk governance. This is not to say that we have wholeheartedly adopted the best-practice models advocated in various international and domestic benchmarks and guidelines. Realistically these models are in a state of development and are yet to crystallise into a truly unified approach [chapter 12]. Indeed, some of the deliberative risk governance principles I expounded above are so embryonic that they have only really taken

[2] *ibid.*

form subsequent to the enactment of the GTA (in benchmarks such as the National Health Partnership Guidelines). Thus, whilst the GTA was enacted at a time when deliberative risk governance was strongly encouraged by various guidelines and benchmarks – and demanded by the public – legislative drafters had little guidance on the best mechanisms to ensure the hope of participatory regulation.

Given the processes of deliberative risk governance will continue to evolve, mature and crystallise, it is important to maintain the flexibility to ensure the regulatory framework is in keeping with domestic and international best practice. On the other hand, the drive towards a deliberative risk governance system derives from a demand for process legitimacy – that is, an institutional guarantee of public participation. This creates somewhat of a conundrum for legislative drafters who must balance between these two regulatory imperatives. Such a conundrum is evident in the GTA.

Deliberative Risk Governance Principles within the GTA. The GTA *does* contain a variety of provisions to ensure that the community and various stakeholders are informed about all aspects of the risk governance system. There are also mechanisms to allow the public to contribute to all aspects of *making, doing and enforcing* law [chapters 16, 17, 18]. There are several points in the risk governance process where the Regulator must consider the opinions of outside bodies, including the community. Most importantly, the GTA creates a community specific committee (the Community Committee), intended to bring the consultative process to the heart of gene technology risk governance [chapter 15]. Hence, the Act creates a nexus for the regulatory agency, scientists, stakeholders and the public to cooperate in the oversight of gene technology.

The GTA *does not,* in many instances, actually compel deliberation with stakeholders and the public. First, the requirement upon the decision maker (Ministerial Council/Regulator) to seek input from the community is generally directory in nature, and can often be tempered or avoided altogether. Secondly, whilst core deliberative risk governance structures do exist in the GTA (such as the Community Committee), they are not truly integrated into the Act and there is

little guidance on how they are to operate in the ordinary course of regulating [chapter 15]. These structures seem to have been inserted into the GTA with the understanding that they were necessary, but without a firm comprehension of how they should operate. Finally, the GTA does not oblige proactive deliberation [chapter 17]. It is passive, assuming the community will bring their concerns to the Office of the Gene Technology Regulator (OGTR), rather than the OGTR actively seeking out interested parties who might be affected by regulated activity.

There are then, institutional mechanisms within the GTA which ensure deliberative risk governance, but, on the whole, legislative drafters did not go one step further and compel their use or truly integrate them into the decision making process. I have argued that there seems to be a philosophy underlying the Act that the public sentiment towards gene technology will die down, and the concern will dissipate, so that the public involvement provisions will be less imperative and indeed somewhat obstructive to the ongoing operation of the regime [chapter 17]. Hence, the GTA allows for the deliberative components of risk governance to be wound back, or at least applied with less vigour. Yet, the technological revolution is not about rewinding, it involves an unceasing progression and expansion. It will present us with as many dilemmas twenty years from now as it did twenty years ago when Justice Kirby warned of the potential demise of the law and the demise of democracy. We should be creating democratic structures that can be built upon, not ones that can be taken down at some later stage.

Deliberative risk governance is essentially about ensuring that our legal institutions remain democratic regardless of their restructure and reform. Democracy is something we all benefit from and which the vast majority of us advocate but also something about which many of us can become lackadaisical. Hence society has seen it necessary to compel participation in, and maintenance of, fundamental democratic institutions. It is for this reason that voting is compulsory in Australia, and the reason government is obliged to undertake certain procedures to ensure it remains fair and representative. However, the technological revolution and legal counter-revolution have collectively diminished the importance of the 'triennial visit to a polling booth'.[3] Deliberative risk

[3] *ibid.*

governance has been established to fill the democratic gap created by those revolutions.

I do not advocate making it an obligation for every aspect of the risk governance process to be undertaken in a comprehensive and participatory manner. Like every other aspect of regulating, we must find a balance point between political extremes. I have noted above that certain aspects of deliberative risk governance must remain flexible to allow for improvement. I have emphasised in the body of this thesis that deliberative risk governance too, has its pitfalls, and should contribute to, not replace the decision-making process. However, there are certain aspects of regulation that might, before the technological revolution, have been considered matters solely within the jurisdiction of Parliament, but because of the system of law we have adopted, can no longer be. For example, where we might once have expected public standards to be enshrined in legislation passed by Parliament, this is no longer possible because of the speed of technological progress. However, it does not mean we should dismiss the importance of community input (either directly, or indirectly through Parliament) in this process.

I would suggest that the aspects of regulation that *must* involve community input include changes to the scope or operation of the regulatory structure, particularly with relation to alterations of the hard law (legislative review) and soft law that directs the standard setting process (the regulations, policy principles and policy guidelines). I would further include as fundamental, any new technology that is to be released into the environment or marketplace for the first time (licensed dealings). I contend that, in Parliament's absence, the decision maker should be obliged to consider such matters in partnership with the community. So too is it justified, in these few instances, to mandate that the OGTR proactively seek out and invite to the deliberation, those whose rights or interests might be impacted upon. Whilst certainly the GTA allows and – read in context of external guiding principles – strongly encourages such practices, it does not wholeheartedly accept them as fundamental to process legitimacy.

Deliberative Risk Governance Principles in Regulatory Culture. The conundrum of simultaneously maintaining regulatory flexibility (including flexibility to

update risk communication where necessary) and ensuring process legitimacy (particularly relating to public involvement) means that altering the Act can only ever provide half the solution. Because the GTA is less than prescriptive about risk analysis, much of the practical application of risk governance will be subject to the processes, principles and attitude adopted by the key regulatory bodies within the framework (the Regulator, OGTR, Community Committee and Ministerial Council). The GTA has left the door open to the concept of deliberative risk governance but now it is up to these bodies to build the practical and conceptual frameworks that pay more than lip service to the concept of a democratic regulatory process.

As of yet it has been the OGTR that has taken up the main responsibility for constructing such frameworks. In many areas the approach of the OGTR to public involvement is laudable and goes beyond the benchmarks set out in the legislation itself. This is particularly true of information translation and target communication, with the office working particularly hard on finding ways to translate risk assessment and management information into hierarchal categories that different audiences can engage with and understand [chapter 16]. The willingness of the OGTR to consult from the outset of the Risk Assessment process to date also evinces a willingness to respond to the spirit of the legislation rather than the letter of the law [chapter 17].

There is then a very open attitude towards public involvement in regulatory practice and the conceptual and practical frameworks developed by the OGTR. The agency has provided a conduit through which risk information can flow and through which the public can scrutinise and contribute to the ongoing operation of the regime. Active consultation and input is encouraged throughout the process of regulating. That is, at least where it relates to human health and the environment.

Whereas there is an institutional recognition of the broader social and ethical risks posed by gene technology within the GTA proper, there seems to be an indication in regulatory policy and practice that such concerns about risks have no place in active involved deliberation. This is immediately obvious by the narrow definition of risk and risk assessment under the current OGTR risk assessment framework.

It is also highlighted in risk assessment and risk management plans, where objections that do not relate to human health and safety or the environment are dismissed as being 'outside the scope' of risk analysis. Instead, these are treated as matters of *general* concern and afforded a non-specific, non-binding and apparently non-risk status. However, even if citizens do want to raise general concerns that don't relate to specific dealings, there is no clear way for them to do this. As of yet, the Community Committee does not consult with the public itself (or even have its own email address on the OGTR website) and the OGTR has left general public engagement to another body altogether (Biotechnology Australia).

As of yet, the applications to the OGTR have related to simple agricultural modifications, such as herbicide resistance and tolerance. What will happen if and when more contentious technologies – for instance terminator technology, transgene/transkingdom organisms [see 2.3.6], or other yet to be realised outcomes of this new revolution – come on to the Australian scene? How the potential social, moral, ethical, legal or economic objections to individual applications such as these are dealt with will be the real test of the OGTR's willingness to engage with the public on their terms and respect the broader risk perception in the community.

What is also somewhat disturbing is the indication by the OGTR that the Community Committee lacks the 'expertise' to 'qualify' it to comment on the risks posed by gene technology. If that is the case, then it would follow that the community proper has no such expertise either. Thus, even if consultation on licence applications is *officially* obliged by the Act, regulatory practice intimates they won't *actually* be taken very seriously because the community really isn't 'qualified' to partake in technical and scientific risk dialogue. The fact that such concerns were voiced within the Community Committee itself, indicates just how entrenched the technically oriented view of risk is in some quarters and the potential for technocratic recidivism to creep into regulatory practice.

The OGTR's narrow view of risk is very much a product of an attitude and culture within the agency, not a parliamentary mandate or legislative directive within the Act. Whilst the GTA makes it clear that human health and safety and the

environment are core and primary concerns that must be taken into account in risk governance it does not state anywhere that these are the *only* concerns that should be taken into account. Indeed, the addition of ethics and community committees into the process indicates an institutional recognition of the plurality of risks posed by the technology. The assertion by the OGTR that the community was 'exclusively' concerned with physical risks does not hold weight either. Whilst the community was very concerned about the health risks of genetically modified food, the debate in Australia, as elsewhere, was driven by a broader range of fears and concerns – one of the primary ones being that the risk governance process should 'take into account more than just science'.[4] Nor is the OGTR's position justified by reference to international or domestic risk analysis standards. The primary international (Codex/Sanitary and Phytosanitary Agreement) and domestic (National Health Policy) guidelines *do* permit the consideration of psychosocial and economic hazards within risk assessment [see 7.2.1]. Thus, it can be seen that adopting a narrow definition of risk is a *choice* on the part of the OGTR; not something obliged by legislation, the community or best practice.

As Jasanoff rightly notes:

> Participation alone … does not answer the problem of how to democratize technological societies. Opening the doors to previously closed expert forums is a necessary step – indeed, it should be seen by now as a standard operating procedure. But the formal mechanisms adopted by national governments are not enough to engage the public in the management of global science and technology. What has to change is the *culture* of governance …[5]

Cultures – regulatory or otherwise – rarely change rapidly or independently. They are influenced by exposure, experience and understanding of and communication with, outsiders. What the GTA has done is to create set the stage for such interaction, even if, at the moment, what is being communicated about may not be as broad as some hoped. Because of the openness, transparency and consultation

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[4] *ibid.*

[5] Jasenoff S, 'Technologies Of Humility: Citizen Participation In Governing Science' (2003) *Minerva* ***41:****238.*

requirements within the GTA the OGTR *will* be exposed directly and indirectly to the public throughout the course of its operation. Community perspectives will also be communicated to it through a variety of avenues. It will experience a broader risk discussion, if only with its internal community and ethics committees.

Whether such interactions and exchanges are sufficient to change regulatory culture is yet to be seen. The community and the committee that represents it will now have a part to play in changing regulatory culture by actually becoming *involved* and exerting at least a political influence over the agency, something capture theory says *can* make an impact upon regulatory attitudes. The question is if the public will be interested enough to maintain continued scrutiny and pressure. The 'diversity of possible futures'[6] for gene technology means that we cannot completely predict whether this is the case, but the fact that we live in a blame society suggests that the concern about each new use of the technology will not go away any time soon. However, perhaps twenty years hence we will not look back and ask, 'what have we done?' – or more aptly 'what has been done on our behalf'? Instead we might be able to state, 'look at what we have achieved together'.

[6] Giddens *op cit* 1.

APPENDICES

APPENDIX 1 :

ROLE OF ADVISORY COMMITTEES ESTABLISHED UNDER THE GENE TECHNOLOGY ACT

Responsibilities	Technical Committee	Ethics Committee	Community Committee
Advice as to Licence Functions of the Regulator	Scientific & Technical Advice on licence applications	None.	General concerns in relation to licence applications
Advice as to use of GMOs	Scientific & Technical Advice relating to -gene technology, GMOs, GM products - biosafety	Ethical Use of Gene Technology.	General concern
Policy Principles	Need & Content	Need & Content in relation to dealings with GMOs that should not be undertaken for ethical reasons (not GM products)	Need & Content
Policy Guidelines	Need & Content	NONE	Need & Content
Codes of Practice	Need & Content	Need & Content in relation to conducting dealings with GMOS (not GM products)	Need & Content
Technical Guidelines	Need & Content		Need & Content
Procedural Guidelines	Need & Content		Need & Content
Appointment	The Technical Committee	the Ethics Committee	the Community Committee
Represented By	Scientific (primarily from the fields of biology, genetics and biotechnology)	Ethicists (environment; applied; legal, religious; population health; agricultural practices; animal health/welfare;	Community Representatives (environment; consumer; community; industry; research; public health; primary production; local government)

		consumer; environmental systems)	
Compulsory Members	- Layperson - Member of the Ethics Committee - Member of the Community Committee	- Member of the Technical Committee - Member of AHEC	- Member of the Technical Committee - Member of the Ethics Committee
Expert Advisors	YES	YES	NO

APPENDIX 2 :

GUIDE TO 'SOFT-LAW' MECHANISMS UNDER THE GTA

	Policy Principles	Policy Guidelines	Codes of Practice	Technical Guidelines	Procedural Guidelines
Issued By	Ministerial Council	Ministerial Council	Ministerial Council	Regulator (27(d))	Regulator (27(d))
Developed By	Ministerial Council - can request Regulator to draft (s27(c))	Ministerial Council - can request Regulator to draft (s27(c))	Regulator (s27(c))		
Bodies that must agree	None, BUT disallowable by CWLTH parliament. (s46A Acts Interpretation Act)	-	None, BUT disallowable by CWLTH parliament. (s46A Acts Interpretation Act)		
Required to be formulated in accordance with ..	Guidelines on consultation issued for the purposes of s22 GTA by the Ministerial Council	-			
Bodies that must be consulted	The Technical Committee Regulator (ss 22(1)(b),27(c)) the Community Committee the Ethics Committee Relevant Commonwealth & State	None	The Technical Committee the Community Committee the Ethics Committee Relevant Commonwealth & State Agencies Relevant		

	Agencies Relevant Industry Groups Relevant NGOs		Industry Groups Relevant NGOs		
Relate to	- Ethical issues relating to Dealings with GMOs - Areas under state law preserving GM or non GM crops for marketing purposes - Dealings with GMOs prescribed by regulations for the purpose of s21 GTA, which do not derogate from the health and safety of people or the environment.	s56 (d) GTR to have regard to (d)any policy guidelines in force under section 23 that relate to: (i)risks that may be posed by the dealings proposed to be authorised by the licence; or (ii)ways of managing such risks so as to protect the health and safety of people or to protect the	Gene Technology. (s24(1))	GMOs (generally?) (27(d)) - requirements for the certification of containment facilities to a certain level. (s90) - requirements for the accreditation of organisation under Pt7Div3 (s 98 (1))	GMOs (generally?) (27(d)) - requirements for the certification of containment facilities to a certain level. (s 90). - requirements for the accreditation of organisation under Pt7Div3 (s 98 (1))
Application to Regulator	Cannot issue licence inconsistent with policy principle. s(57)	- Must 'have regard' to principles when considering license. (s56)	- Must consider need for before entering organism on the GMO register (79(2)(c))	- Must consider need for before entering organism on the GMO register (79(2)(c))	- Must consider need for before entering organism on the GMO register (79(2)(c))

Application to Licensee	None	None	May be required as a licence condition (s62(l))	May be required as a licence condition (s62(l))	May be required as a licence condition (s62(l)) - may be on GMO register (79(2)(c))

APPENDIX 3:

STAKEHOLDER GROUP INPUT TO HOUSE & SENATE INQUIRIES[1]

Primary Industry	Secondary Industry	Government	Public-Interest	Public Research	Individuals
Australian Barley Board [H]	AgrEvo/Aventis PtyLtd [H][S]	Agriculture, Fisheries and Forestry Australia [H]	Australian Centre for Environmental Law [S]	Australian Cotton Co-operative Research Centre (NSW) [S]	82 Submissions by members of the public to both Houses.
Australian Cotton Growers Research Association Inc. [H][S]	Agrifood Alliance/Awareness Australia [H][S]	Australia New Zealand Food Authority [H]	Australian Conservation Foundation [S]	Centre for Legumes in Mediterranean Agriculture [H]	
Australian Raw Sugar Industry [H]	Agritrade Int. Pty Ltd [H]	Australian Academy of Science [H]	Australian GeneEthics Network - Perth (WA) [S]	Cooperative Research Centre for Premium Quality Wool [H]	
Australian United Fresh Fruit & Vegetable Association Ltd [H] [S]	Animated Biomedical Productions [H]	Australian Law Reform Commission [S]	Australian GeneEthics Network (Vic) [H][S]	Cooperative Research Centre for Tropical Plant Pathology [H]	
Bio-Dynamics Tasmania [S]	Australian Biotechnology Association [H] [S]	Australian Quarantine and Inspection Service [H]	Canberra Consumers Inc [S]	Cooperative Research Centre for Weed Management Systems [H]	
Cattle Council of Australia [H]	Australian Food and Grocery Council [H][S]	Department of Foreign Affairs and Trade [H]	Consumer Food Network of the Consumers' Federation of Australia [S]	Cooperative Research Centres Association Inc. [H]	
Cattlemen's Union of Australia Inc. [H]	Avcare Ltd [H] [S]	Department of Health and Aged Care [S]	Consumers' Association of South Australia Inc [S]	CSIRO [H] [S]	
Dairy Research and Development Corporation [H]	AWB Ltd [H][S]	Department of Industry, Science and Resources [H]	Environment Centre of WA [S]	Rural R&D Chairs Committee [H]	
Grains Council of Australia [H]	Cotton Research and Development Corporation [H]	Department of Primary Industries, Water and Environment (TAS) [S]	Friends of the Earth (Fitzroy) [S]	Southern Cross University [S]	
Meat and Livestock Australia Limited [S]	Dow AgroSciences [S]	District Council of Grant [S]	Friends of the Earth (Perth, WA Group) [S]	WA State Agricultural Biotechnology Centre, Murdoch University [H]	
National Farmers' Federation Australia [H] [S]	Du Pont Technical Centre [S]	Environment Australia [H]	GE-Free Tasmania [S]	Waite Institute,	
	Florigene Limited and Nugrain Pty Ltd [S]				

[1] Compiled from data from House & Senate Inquires see:
<http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> AND
<http://www.aph.gov.au/house/committee/primind/gtinq/subs.htm> respectively (13/1/03).

NSW Farmers' Association [H][S] NT Bio Dynamic Network (NT) [S] Organic Federation of Australia Inc (VIC) [S] Organic Federation of Australia Inc. [S] [H] Pastoralists and Graziers Association of WA Inc. [H] Queensland Fruit & Vegetable Growers [H] South Australian Farmers Federation [S]	Food Industry Council of Tasmania [S] Forest & Wood Products Research and Development Corporation [H] Frontier Seeds Pty Ltd [H] Go Mark Food Systems [H] Grain Biotechnology Australia Pty Ltd [H] Grains R&D Corp. Ltd [H] [S] Heritage Seed Curators [H][S] Insurance Council of Australia Ltd [H][S] Monsanto Aust Ltd [H] [S] Novartis Australia Pty Ltd [H][S] Nugrain Pty Ltd [H] Seed Industry of Australia [S] Serve-Ag Pty Ltd [S] Tasmanian Alkaloids Pty Ltd [S] Valley Seeds Pty Ltd [S] Veterinary Manufacturers and Distributors Association [H] Waratah Seed Co.	Interim Office of the Gene Technology Regulator [H] IP Australia [H] Dick Adams MP (TAS) [S] National Health and Medical Research Council [S] Natural Law Party [H] NSW Government [H] Qld Government [H] [S] Qld Government: Office of Fair Trading, Department of Equity and Fair Trading [H] Senator Minchin [H] Senator Stott-Despoja [H] S.A Government [H] [S] Tas Government [H][S] Vic Government [H] [S] W.A Government [H][S]	Institute of Public Affairs Ltd (VIC) [S] National Association for Sustainable Agriculture, Australia Ltd. [H] National Council of Women of Australia [S] National Genetic Awareness Alliance [H][S] Public Health Association of Australia Inc. [H] Residents Against Genetically Engineered Food [S] World Wide Fund for Nature and The Humane Society International [S]	University of Adelaide [S]	

	Ltd [H]				
[H] 8 [S] 5 [H][S] 5 44% 28% 28%	[H] 10 [S] 8 [H][S] 11 35% 27% 38%	[H] 14 [S] 5 [H][S] 5 58% 21% 21%	[H] 2 [S] 14 [H][S] 2 11% 78% 11%	[H] 7 [S] 3 [H][S] 1 64% 27% 9%	[H] 15 [S] 65 [H][S] 1 19% 80% 1%
Total : 18 Representation: 10%	Total : 29 Representation:16%	Total : 24 Representation:13%	Total :18 Representation:10%	Total :11 Representation: 6%	Total :81 Representation:45%

APPENDIX 4 :

PARLIAMENT & CONTROL

This Appendix expands upon statements in the main text relating to the power of Parliament and the obligation for Parliament to exercise that power according to the will of the people. Moreover, it explains why in situations where another agent begins to control societies fate, Parliament must step in and legislate. It will then examine the form of legislation that is most relevant to controlling gene technology.

SOVEREIGNTY AND POWER

Under the Australian legal system all legal power derives from the Federal Constitution.[1] Any law or power exercised under the claim of law, which is shown to be outside the grant of the Constitution, is invalid and of no effect.[2] The Federal Constitution demarcates specific areas of power for the Federal Government and residual areas of power for the States, so that the two levels of government cooperate in a power sharing arrangement, referred to as the 'Crown'.[3] Both these bodies are empowered to make laws for the 'peace order and good government' of their respective jurisdictions.[4] The words 'peace order and good government' do not limit the respective powers of either Parliament, and cannot be limited by judicial interpretation, because this is considered a question of policy for the Parliament to decide.[5] Collectively there is no area for which they cannot make laws.

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[1] ss 51, 52, 109 *Commonwealth of Australia Constitution Act* 1900

[2] *Riverina Transport v Victoria* (1937) 57 CLR 327, 341-2 per Latham CJ.

[3] Therefore, although a sovereignty among nations may thus be indivisible, the internal sovereignty may be divided under the form of government which exists. However, that does not mean that external sovereignty and internal sovereignty are in kind different. Sovereignty in each case has the same content, the right and power to govern that part of the globe". *New South Wales v The Commonwealth* (1975) 135 CLR 337, at 480.

[4] s 51. *Commonwealth of Australia Constitution Act* 1900

[5] *Reg. v Foster; Ex parte Eastern and Australian Steamship Co. Ltd.* (1959) 103 CLR 256, per Windeyere J. at 308. *Union Steamship v King* (1988) 166 CLR 1;. The one limitation is that State Governments cannot limit

> There is no gap in the constitutional framework. Every power right and authority … is vested in and exercisable by the Crown in Australia subject only to the Constitution. [6]

Therefore, collectively and cooperatively the internal governments of the Australian federation have complete control over Australia and everyone in it. This overarching power is referred to as 'sovereignty' (deemed parliamentary or crown sovereignty).[7]

Sovereignty. It is the Crown, which is recognised 'under the law of nations' as having the 'power and right' to govern completely and effectively to the exclusion of all others.[8] It is the right of the Crown to 'lawfully say to another "Thou shalt" or "Thou shalt not" to any within its jurisdiction.[9] No other can subvert that power, and the Crown exercises its 'powers in absolute freedom, and without interference or control whatever except that prescribed by the Constitution

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their own powers. Only the Commonwealth can do this, with the express consent of all State parliaments (s 15. Australia Acts)

[6] *ibid*, at 498.

[7] Sovereignty, in its classical sense, is marked by two main elements. First, a sovereign is not subject to the commands of any other person Second, within the limits of the sovereign's jurisdiction, everyone is subject to the commands of the sovereign.[Austin J, *Lectures on Jurisprudence*, Vol. 1, 5th ed. John Murray, London, 1885, pp 225-26.] I term this form of sovereignty as the 'classical' form of sovereignty, because it cannot truly be said to be representative of the form of sovereignty found in most modern day governments, including Australia. Clearly, two separate governments (being state and federal) cannot both have sovereignty over the same territory, because one cannot have absolute control over a territory and also be subject to another's commands. A fact recognised soon after federation. 'a right of sovereignty subject to extrinsic control is a contradiction in terms.' *D'emden v Pedder* (1904) 1 CLR 91, at 110. However, the 'Crown' is now recognised as being a single indivisible sovereign under the law of nations (externally) and mutual or shared sovereignty within the nation. Therefore, although a sovereignty among nations may thus be indivisible, the internal sovereignty may be divided under the form of government which exists. However, that does not mean that external sovereignty and internal sovereignty are in kind different. "foreign sovereigns are not concerned with the manner in which a sovereign state may … exercise its powers or with the fact that the right to exercise those powers which constitute sovereignty may be divided vertically or horizontally in constitutional structure within the State", *New South Wales v The Commonwealth* (1975) 135 CLR 337, at 480.

[8] *ibid*, at 498.

[9] *Commonwealth v The State Of New South Wales (Railway Servants Case)* (1906) 3 CLR 807, per Griffith CJ, Barton and O'Connor JJ. At par 9.

itself'.[10] Most importantly sovereignty means that 'there is no power which …. can come into rivalry with the legislative sovereignty of Parliament'.[11]

Sovereignty in the Risk Society. Crown sovereignty is therefore about *power.* It is about the power of complete control over all matters within a territory. It is the power, vested solely in the state and federal parliaments, to control the fate of a place and its populace. The notion of Crown sovereignty is both parallel to, and potentially in conflict with, the status of technology in the risk society. It parallels technology in the risk society, because it places the fate of society as a whole, as well as the individuals within that society, in the hands of actual human agents, being the members of the parliaments of the Commonwealth.

Technology potentially conflicts with the notion of Crown sovereignty because, if technology is as influential as the blame society perceives, it undermines the freedom of the Crown to exercise complete control over its territory and everyone in it. That is, if technocrats are to blame for society's fate, then Parliament cannot be said to have absolute control.

AN OBLIGATION TO CONTROL

There is a fundamental difference between *allowin*g something to have free reign and something having *complete* free reign. Thus, if the Crown 'permits' technology to change the fate of society, either because it approves of the direction the technology is taking society, or it is simply disinterested in the outcome, there is no diminution of sovereignty.

I would argue that the risk society demands that the Crown not be indifferent, nor neutral to the implications of technology, because to do so is contrary to the purpose of Crown sovereignty itself. Thus, I contend that it was both justified and necessary for the Crown to enact the GTA. I base this argument on the following rationale:

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[10] *D'Emden v Pedder* (1904) 1 CLR 91 at 110-111.

[11] Dicey A.V, *Introduction to the Study of the Law of the Constitution.* 10th ed. Macmillan, London, 1915/1959 (reprint) pp 69-70.

- absolute crown sovereignty no longer exists in its classical sense. Rather, the manner and form of the exercise of sovereign power is proscribed by the Constitution;
- underlying the Constitution is the fundamental principle of unlimited popular sovereignty;
- the Crown exercises its limited sovereignty as an agent of the people;
- the people, as absolute unlimited sovereigns, have vested complete control in the Crown and *only* the Crown to control the fate of the people and their territory;
- there is then an implied obligation for the Crown to ensure it maintains sole and complete control of the fate of the people and their territory;
- the constitutional framework allows only the Crown to intervene in the public interest through the device of law; and
- because the Crown is obliged to maintain control over the fate of the people, it must intervene in technological development, in the form of laws which protect the public interest.

The basis for these arguments is expanded upon below.

The Constitution. The Constitution 'forms and moulds the political forces of the nation',[12] it grants power to and prescribes the limits of power of the respective state and federal parliaments. So whilst there is 'no gap' in the powers held cooperatively by the state and federal legislatures, they remain 'subject … to the Constitution'.[13] Subjecting the Crown to prescribed rules seems, on its face, contrary to the principle of absolute power. [14] To understand why this is the case

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[12] Galligan B, 'Judicial Review in the Australian Federal System: Its Origin and Function', (1979) *Federal Law Review* 4:**10**:367.

[13] *New South Wales v The Commonwealth* (1975) 135 CLR 337, at 498.

[14] If however, for the reasons outlined above, the Constitution is merely to be seen as a compact between state and federal governments, that divides the powers between two mutual sovereigns over the same territory, then its existence would not seem to undermine the sovereignty of the Crown, at least from the external perspective. Note that, although the Constitution brought the Federal Governement into existence, it is still considered to have full legal effect at the creation of that document. 'Like the goddess of wisdom the Commonwealth *uno ictu* sprang from the brain of its begetters armed and of full stature. At the same instant the Colonies became States'. *Uther v FCT; Re Foreman and Sons Pty Ltd* (1947) 74 CLR 508. at 531. The intergovernmental compact argument had some early support, but this has all but been extinguished for the popular compact model. [see text].

we must understand the basis of the constitution and on what justification it vests sovereignty in the Crown.

A Compact Of The 'People'. There was some early support for the view that the Constitution was 'in the nature of an agreement among sovereign powers to give up some of their power to a new central body'.[15] Nevertheless, even among those who originally favoured the concept of an intergovernmental compact,[16] there was recognition that the Constitution was more than a mere legal document. The special nature of the Constitution arose not merely because it was the cornerstone of the legal system but also because of the primacy given to the peoples of Australia in both the document itself,[17] and the democratic form in which it was passed and premised upon.[18]

The importance of the people to the constitutional framework and the insufficiency of the intergovernmental compact argument was confirmed by the High Court in the *Engineers* case.[19] In *Engineers,* the Court asserted that the constitution was not a treaty between independent sovereign states but the creation of a completely new system of government, as the result of a 'political compact of the whole of the people of Australia, enacted into binding law by the Imperial Parliament'.[20] As such, the power of the Crown arose by virtue of 'a the grant of legislative power to the Commonwealth Parliament as representing the *will of the*

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[15] Zines, *The High Court and the Constitution* 3rd ed. Butterworths: Sydney, 1992, p 1. *Federated Amalgamated Government Railway and Tramway Services Association v NSW Railway Traffic Employees' Association* (*Railway Servant's Case)* (1906), 4 CLR 488; *D'Emdem v Pedder* (19041 CLR 91; *A-G (Cth) v Colonial Sugar Refining Co Ltd* (1913) 17 CLR 644 at 655.

[16] Specifically the High Court pre Engineers Case [*Amalgamated Society of Engineers v Adelaide Steamship Co Ltd* (1920) 28 CLR 129].

[17] The Preamble of the Constitution speaks of 'the people' of the states of Australia, having 'agreed to unite in one indissoluble Federal Commonwealth'.

[18] Then Constitution was adopted subsequent to a majority of electors in each state voting in referendum to adopt accede to the Federal Bill. For a history of the drafting of the Constitution see Quick J, Garran R.R, *The Annotated Constitution of the Australian Commonwealth*, Legal Books, Sydney, 1901/1976(reprint); . Booker K, Glass A, Watt R, *Federal Constitutional Law: An Introduction.* Butterworths, Sydney, 1994. chpt 2.
The 'democratic form it was premised upon' derives from its foundation in American tradition, and the acceptance of the Rousseauean doctrine of social contract propounded by the US Supreme Court in *Marbury v Maddison* (1803) 1 Cr. 137, see in text.

[19] *Amalgamated Society of Engineers v Adelaide Steamship Co Ltd* (1920) 28 CLR 129.

[20] *ibid.* at 342.

whole of the people [emphasis added] of all the States of Australia'.[21] This position is confirmed by the preamble of the Constitution, which specifically states that it is the 'people' of Australia' who have 'agreed to unite in one indissoluble Federal Commonwealth'. It is now the favoured[22] interpretation of the status of the constitutional structure, that the constitutional basis for the constitution lies in the *will of the people*.[23]

As a compact of equal people rather than a compact of sovereign states, the Constitution creates a prescribed legislature, because the Crown is subject to rules created by another body, 'the people'. This seems to contradict the well accepted doctrine that the Crown is 'sovereign' because it necessarily implies that it is the people as a whole, not the Crown, who possess absolute power, so vested in the Federal Government. Both the verification of this principle and the resolution of the seeming legal quandary it creates can be clarified by examining the historical basis for the adopted architecture of the Constitution.

POPULAR SOVEREIGNTY

Sovereignty in the American System. Contrary to popular belief the constitutional framework was designed, not as a 'summary of the British

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[21] *ibid*., at 153.

[22] I say 'favoured' because the notion of an intergovernmental compact has not been completely destroyed. See *West Australian Psychiatric Nurses' Assosciation v Australian Nursing Federation* (1991) 102 ALR 265, This position however has been criticised, see Booker, K, Glass A, Watt R, *Federal Constitutional Law; An Introduction*, Butterworths, Sydney, 1994. p 245

[23] Expressed concisely by Barwick CJ in the *Payroll Tax Case* [*Victoria v Commonweatlh* (1971) 122 CLR 353] The Constitution does not represent a treaty or union between sovereign and independent States. It was the result of the will and desire of the people of all the colonies expressed both through their representative institutions and directly through referenda to be united in one Commonwealth with an agreed distribution of governmental power.", at 370 per Barwick CJ.

Thus, the Court in *Leeth v Commonwealth* (1992) 174 CLR 455., described 'the conceptual basis' of the Constitution as:

the free agreement of "the people" - all the people - of the federating Colonies to unite in the Commonwealth under the Constitution. Implicit in that free agreement was the notion of the inherent equality of the people as the parties to the compact. *ibid.* at para 9.

experience'[24] but rather 'framed after the pattern of that of the United States'.[25] This is in no way an assertion that our legal system is an American derivation, it is not and the High Court has, on several occasions, warned against looking to that jurisdiction for guidance on the process of law here.[26] However, the way in which Parliament is constituted; the bicameral nature of the Crown; and limited Crown sovereignty, are all features of the American system co-opted into the British tradition.[27]

Thus, to truly understand what the constitutional founders intended for Crown sovereignty to mean within our federal system we can look to what they understood it to mean within the federal system they adopted it from.[28] As will be examined directly below this is justified, because the principle of Crown

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[24] Archer J.R., Maddox G, 'The 1975 Constitutional Crisis in Australia.' (1976) *Journal of Commonwealth and Comparative Politics* **14**:147.

[25] Dixon O, *Jesting Pilate* 1st ed., The Law Book Company, Melbourne 1965/1996(reprint), p. 101. for an in depth discussion of the American influence on the Australian Constitution see Galligan B. 'Judicial Review in the Australian Federal System: Its Origin and Function'. (1979) *Federal Law Review*, 4:**10**:367-397.

[26] *Engineers Case* (1920) 28 CLR 129, at p 146, *New South Wales v The Commonwealth* (1915) 20 CLR 54, at 79, *Duncan v Queensland* (1916) 22 CLR 1, at 603.

[27]As Galligan notes, "The Australian founders grafted the American federal system onto the traditional British executive of responsible government. Though federalism was by then a mature and well-tried system of government in North America, it was quite novel to the Australians ... The Australian founders adopted the American formulation" Galligan B, 'Judicial Review in the Australian Federal System: Its Origin and Function', (1979) *Federal Law Review* 4:**10**:372.

[28] Reference to the historical nature of the Constitution is relevant to determining its purpose because 'in Australia it has been accepted that in construing the Constitution ... regard may be had to the state of things existing when the ... [Constitution] was passed, and therefore to historical facts and to earlier legislation.' *A-G (Cth); Ex rel McKinlay v Commonwealth* (1975) 135 CLR 1 per Gibbs J at 47.

It has long been recognised that the US federal system can be considered relevant to understanding what the Constitutional founders meant in the Australian federal context. The Privy Council noted this almost immediately after federation: "In fashioning the Constitution of the Commonwealth of Australia the principle established by the United States was adopted in preference to that chosen by Canada. It is a matter of historical knowledge that in Australia the work of fashioning the future Constitution was one which occupied years of preparation through the medium of conventions and conferences in which the most distinguished statesmen of Australia took part. Alternative systems were discussed and weighed against each other with minute care. The Act of 1900 must accordingly be regarded as an instrument which was fashioned with great deliberation, and if there is at points obscurity in its language, this may be taken to be due not to any uncertainty as to the adoption of the stricter form of federal principle, but to that difficulty in obtaining ready agreement about phrases which attends the drafting of legislative measures by large assemblages." *Attorney-General for Australia v Colonial Sugar Refining Co*, 32 T.L.R., at p. 445, per Haldane L.C at 651.

sovereignty adopted by our American cousins has been accepted as axiomatic in the Australian legal system.

In the US the seminal discussion of Parliamentary sovereignty within a federal democracy was discussed by Marshal CJ in *Marbury v Madison.*[29] The Court in that instance was required to justify the power of the judiciary to review the constitutionality of Parliamentary exercises of power. Allowing the Court to review and invalidate acts of Parliament is to diminish the absolute power of that body. Marshal CJ argued;

> That the people have an original right to establish, for their future government, such principles, as, in their opinion, shall most conduce to their own happiness, is the basis on which the whole American fabric has been erected. The exercise of this original right is a very great exertion; nor can it, nor ought it, to be frequently repeated. The principles therefore, so established, are deemed fundamental. And as the authority from which they proceed is supreme, and can seldom act, they are designed to be permanent.[30]

Marshall's argument is premised on two notions. First, the people retain the fundamental right to decide their own fate (i.e. their 'happiness'). Therefore it is the people, as a whole, who are the ultimate sovereigns. The second premise speaks to rationality. That is, there is a degree of impossibility in the 'people', as a whole unit, being capable of continued, unified governance (i.e. it is a 'very great exertion'). To bring all the people of a nation in a decision making process is such a gargantuan effort that it could not be repeated in respect of each and every decision which affected the fate of that nation. Rather, the nation makes a unique, reasoned undertaking in which it vests powers in a specialist agency to undertake the day to day decision making process.

> This original and supreme will [of the people] organises the government, and assigns to different departments their respective

[29] (1803) 1 Cr. 137.

[30] *ibid.* at 4.

> powers. It may either stop here, or establish certain limits not to be transcended by those departments.[31]

Parliament is, by this rationale, merely a department established to undertake a task set down for it by the people in that one off, 'big bang' constitutional agreement arrived at by the people. Under that agreement the people set out the manner and form in which the Parliament must make decisions relating to society's fate.

Judicial review of parliamentary law making is justified because, as 'it is emphatically the province and duty of the judicial department to say what the law is',[32] it is the only body which can ensure that the agent (Parliament) acts in accordance with the wishes of the principle (the people). Without judicial review, the legislature would be given 'a practical and real omnipotence', or in other words, unlimited sovereignty, which, to Marshall, was completely unacceptable.[33] The very overt implication here is that it is the only body with 'practical and real omnipotence' is the people.

'Axiomatic' in the Australian Context. The principles of *Marbury v Madison* have been accepted *in toto* as a justification for judicial review under Australian Constitutional Law, to the extent that the High Court has stated that 'in our system the principle of *Marbury v Madison*is accepted as axiomatic'.[34]
By accepting Marshall's justification in *Marbury v Madison* for judicial review as being 'axiomatic', the fundamental premises upon which that rationale relies also become axiomatic. Of particular relevance to the current discussion are:

- the express premise, that the people retain the ultimate power to decide their own fate; and
- the unsated premise that the Parliament is the agent of the people.

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[31] *ibid.* at 5.

[32] *ibid.* at 12.

[33] *ibid.* at 16.

[34] *Australian Communist Party v Commonwealth* (1951) 83 CLR 1, 262. Moreover, Sir Owen Dixon (at that time Chief Justice of the High Court), asserted that Marshall's rationale underpinned the Constitution itself, because, 'to the framers off the Commonwealth Constitution thesis of Marbury v Madison was obvious' Dixon, Sir Owen, "Marshall and the Australian Constitution", (1955) *Australian Law Journal* **29**:420.

Both of these principles have become accepted doctrines of constitutional law by the High Court.[35] They were given formal recognition in the Australia Acts which severed completely any subordination to the Imperial Parliament.[36] They will form the basis not only of the present argument but will underpin many of the following arguments on why the government must deliberate and communicate with the people in the regulatory process.

The Purpose of the Overarching Power. From an internal aspect, absolute Crown sovereignty is a legal fiction. The fiction is not however completely overwhelming nor overly broad. The Crown in fact does retain 'every power right and authority', without gaps and without exceptions [see above]. The Parliament is referred to as being 'sovereign', and has the legal right to govern completely and effectively to the exclusion of all others [see above]. The limitation is, however, that this not a power and authority to do all things for *any* purpose. Rather, it is the power and authority to do all things for a *specific* purpose.

Whilst Marshall never expressly dealt with the breadth of power vested in the Crown, it can be necessarily implied from his rationale that the Crown *must* have the power to do all things.[37] The fact that the people 'can seldom act' necessitates the Crown being vested with the widest possible powers. Otherwise, the people would be required to undertake the 'gargantuan task' of decision making as a

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[35]"Australia's Constitution lies in the will of the Australian people." *Durham Holdings Pty Ltd v The State of New South Wales* [2001] HCA 7,177 LR 436, at 75 per Gaudron, McHugh, Gummow and Hayne JJ;
"Governments are the agents of the people … the powers of government in this country are derived from the people who are the ultimate sovereign". *John Anthony Ridgeway v The Queen* (1995) 129 ALR 41 (1995) 69 ALJR 484 per Mc Hugh J.

[36] *Australia Act* 1986 (Cth); Australia Act 1986 (U.K), Lindell G, 'Why is Australia's Constitution Binding? - The Reasons in 1900 and Now, and the Effect of Independence' (1986) *Federal Law Review* **16**:49. It is important to reiterate that, from an external perspective, sovereignty is not diminished by accepting the doctrine of Marbury v Madison, because it merely marks the division of powers within a constitutional structure. That is there is an ultimate sovereign, who has the fundamental, final and complete power to determine the fate of the territory and its people. It does however have a major impact on how sovereignty operates internally.

[37] Marshall argued that unilateral action by the people to establish the Constitution was 'a very great exertion; nor can it, nor ought it be frequently repeated'.

whole body, each and every time a new situation arose, which was outside the scope of the Crown's limited power.[38]

Hence, the people invest the entirety of their power in the Crown as their agent because this is the best way to ensure that their fate is decided in a way that 'shall most conduce to their own happiness'.[39]

The importance of this overarching and unequalled power is not overlooked by the Constitution, nor is it lightly given. It is protected by core principles within the Constitution, which require monitoring and oversight of the Crown's decision making process, by virtue of restricting the manner and form of that exercise of power and by the electoral and judicial process.[40] The people retain the right to remove or alter that power in the form of a referendum.[41] No element of the power can be derogated from or given away.[42] Legislation that inhibits or impairs part of the overall Crown, for instance the continued functioning of the States, will be invalid.[43] Nor can the Parliament ordinarily fetter its powers or the powers of future Parliaments.[44]

The paramountcy of this power and task of the Crown cannot then be understated. It obliges the Crown to act in accordance with the will of the people, for the

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[38] *As O'Connor J stated in Jumbunna Coal Mine: '*it must always be remembered that we are interpreting a Constitution broad and general in its terms, intended to apply to the varying conditions which the development of our community must involve.' *Jumbunna Coal Mine NL v Victorian Coal Miners' Association* (1908) 6 CLR 309. See also Dixon J, 'it is a Constitution we are interpreting, an instrument of government meant to endure and conferring powers expressed in general propositions wide enough to be capable of flexible application to changing circumstances. *Australian National Airways Pty Ltd v The Commonwealth* (1945) 71 CLR 29 per Dixon J at 81.

[39] *Marbury v Madison, op cit,* at 4.

[40] ss. 7, 21,24 *Constitution of Australia* 1900. See the discussion in *Australian Capital Television v The Commonwealth* (1992) 177 CLR 106 F.C. 92/033, particularly that of Mason.C.J.

[41] s.128 *Constitution of Australia* 1900.

[42] Note however, it can be 'delegated', but it cannot be 'abdicated'. V*ictorian Stevedoring & General Contracting Co Pty Ltd v Dignan* (1931) 46 CLR 73 , per Evatt J at 121; *Giris Pty Ltd v Commissioner of Taxation (Cth)* (1969) 119 CLR 365, per Barwick CJ at 373, Kitto J at 379.

[43] *Melbourne City Council v Commonwealth (State Banking Case)* (1947) 74 CLR 31, per Rich J at 66, Starke J at 75; *Commonwealth v Tasmania (Tasmanian Dam Case)* (1983) 158 CLR 1, per Mason J at 139, Brennan J at 215-216.

[44] *McCawley v The King* (1920) 28 CLR 106.

purpose they set out in a continuing and interrupted way.[45] This is the basis upon which the whole 'Australian' fabric has been erected.[46]

There are various sources from which the views of the people may be gleaned. However, it is the Constitution that is paramount and fundamental. Moreover, it is the Constitution that is the clearest expression of the 'views of the people' on behalf of whom Parliament act, because, as the High Court has emphasised, 'Australia's Constitution lies in the will of the Australian people'.[47]

All Power Must Lie With the Crown. The principle purpose of the Constitution is to vest powers in the Crown as the indissoluble, sole and paramount power in the land.[48] The people do not give this power to any other body, they invest it *entirely* in the Crown. The *fundamental* and basic statement of popular will is therefore, that the Crown alone, should be empowered to decide the fate of the territory and the people in it. This is the primary purpose of the Constitution. As the Crown is obliged to exercise its overarching power for the specific purpose set out in the Constitution, its primary concern must be to ensure that no other power diminishes the absolute sovereignty of the people. To do any less would allow technocrats to control the fate of society and thereby undermine the charge placed in Parliament.

Solving the Risk Dilemma. Because the Crown is obliged to maintain its status as the sole agent of the public will and the sole arbitrator of public fate, the first problem of the risk dilemma is solved. That is, the question of who must be in control of public risk decisions *must* ultimately be the Crown. The Constitution

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[45] As Mason CJ asserted in *Australian Capital Television v The Commonwealth*, "The point is that the representatives who are members of Parliament and Ministers of State are not only chosen by the people but exercise their legislative and executive powers as representatives of the people. And in the exercise of those powers the representatives of necessity are accountable to the people for what they do and have a responsibility to take account of the views of the people on whose behalf they act". (1992) 177 CLR 106 per Mason CJ, at 138.

[46] Adopted from *Marbury v Madison,op cit,* , being 'the basis on which the whole American fabric has been erected'.

[47] *Durham Holdings Pty Ltd v The State of New South Wales* [2001] HCA 7,177 LR 436, per Gaudron, McHugh, Gummow and Hayne JJ at 75.

[48] Preamble, *Constitution of Austrlalia* 1900.

requires the Crown to intervene in the risk society so that technology is implemented in a manner reflective of the people's will in it, in a way which 'shall most conduce their own happiness'. Thus, the intervention of the Crown by passing the GTA is both justified and necessary because it reflects an obligation upon Parliament to exercise control. Understanding this, I will move the question of how that control will be maintained and in what form.

THE FORM OF INTERVENTION

Once the question of 'who should decide?' is answered, the problem of 'how should they decide?' must be dealt with. This problem is more complex, not least because of the inherently subjective and value laden nature of risk [see above]. How to make decisions relating to technological risk to best reflect the public will (the manner of intervention) is an issue dealt with over several successive chapters. In the immediate discussion I wish only to deal with the form in which the intervention should take place.

Whilst it can be necessarily imputed that the Crown must intervene in technological risk, the Constitution gives no indication as to what form that intervention should take. For the reasons elucidated upon above, it is necessary for the Constitution to be couched in as broad as possible terms, not limiting either the scope of power nor the form in which it must be expressed.[49] The one limitation is that the Crown's power must be expressed through law. That is, the Constitution empowers Parliament to '*make laws* [emphasis added] for the peace, order and good governance' of the people and their territory. These laws must be passed through a prescribed process, which ensures they are assented to by elected representatives in both houses of Parliament. As noted above, the Constitution

[49] "It is very difficult to maintain the view that the Commonwealth Parliament has no power, in the exercise of its legislative power, to vest executive or other authorities with some power to pass regulations, statutory rules, and by-laws which, when passed, shall have full force and effect. Unless the legislative power of the Parliament extends this far, effective government would be impossible." *Victorian Stevedoring & General Contracting Co Pty Ltd v Dignan* (1931) 46 CLR 73, per Evatt J at 117.

also prescribes the manner and form in which certain laws may be passed by State and Federal Parliaments respectively.[50]

With the exception of these formal requirements, as well as the need to avoid impacting on certain limited implied constitutional rights and liberties,[51] the Constitution makes no mention of the form which the law should take with respect to any one subject matter. Nor have the Courts clarified the issue and will likely never do so, because this is specifically the arena of law that they must avoid by virtue of the separation of powers doctrine.[52] To determine which form of law should be utilised in any instance is inherently a political question, which involves considering whether the law is 'a good one' or 'whether it is just or expeditious'.[53] As Latham CJ stated in the *Communist Party* Case:

> [i]t is not in my opinion a function of a court to determine whether legislation 'goes too far' or is 'incommensurate' or 'is too drastic' or 'is not reasonably necessary'. The only function of a court when the validity of legislation is challenged as ultra vires the Commonwealth Constitution is to determine whether it is legislation 'with respect to' a specified subject matter.[54]

There is, then, no definitive guide to how best to make law with respect to any one subject matter. Nevertheless, the law is relatively succinctly separated into specific areas, categories and classifications as part of the long tradition of legislation and interpretation throughout the Commonwealth. I wish to examine

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[50] With respect to laws passed through the Federal Parliament, the purpose of the law must be in some way connected to a head of power so granted by the Constitution. With respect to laws passed through State Parliaments, there is an imputed obligation to ensure that it does not impede on the Commonwealth jurisdiction.

[51] Such as political debate, discussion and protest. *Minister of Immigration & Ethnic Affairs v Teoh* (1995) 183 CLR 273; *Theophanous v Herald & Weekly Times Ltd* (1994) 182 CLR 104; *Stephens v West Australian Newspapers Ltd* (1994) 182 CLR 211; *Lange v Australian Broadcasting Corporation* (1997) 189 CLR 520.

[52] *Melbourne Corporation v The Commonwealth* (1947) 74 CLR 31, at 82;.

[53] *Fisheries Case* (1898) AC 700 at p 713; 'Courts must be exact in distinguishing between ascertaining that the circumstances over which the power extends exist and examining the mode in which the power has been exercised' *Broken Hill South Ltd v Commissioner of Taxation* (NSW) (1937) 56 CLR 1, per Dixon J, at 375.

[54] *Australian Communist Party v Commonwealth* (1951) 83 CLR 1 per Latham CJ at p 153.

the categories and classifications of law which have developed as part of the legal process.

The Categories of Law. The 'classification of [law] into separate and distinct categories … is comparatively speaking a recent innovation'.[55] However, these categories have been systematically indoctrinated into the process of law making, so that there can be seen to be stable distinctions between the manner and form in which different subject matters are dealt with.

I do not wish to assert here that the Parliament is limited to these categories or legal mechanisms. However, it must be recognised that the common law tradition has been to normalise legal practices so that they are formalised and predictable.[56] The general categories of law discussed below have become so much a part of the legislative system that they could be said to be fundamental institutions.[57] Moreover, these 'distinct categories', were, by the time of Federation in Australia, relatively well accepted as part of the common law heritage.[58] Therefore, it is relatively certain that the law making process envisioned by the constitutional founders would have had these legal categories in mind at the time that the Constitution was enacted.

In opting for the GTA framework the Commonwealth has implemented a public law regulatory regime. I wish to examine, by a process of exclusion, why this was the most suitable category of law for the subject matter, realising that subject matter is part of the overall risk dilemma. However, in examining the benefits and

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[55] Wynes W, *Legislative, Executive and Judicial Powers in Australia*, 5th Ed, Law Book Company, Sydney, 1976, pp 36-37.

[56] "The law must be kept in logical order and form, for an aspect of justice is consistency in decisions affecting like cases and discrimination between unlike cases on bases that can be logically explained" *Dietrich v The Queen* (1992) 177 CLR 292 per Brennan J at para 7.

[57] So accepted are the various forms of legislative intervention that the original High Court argued, "It is too late in the day to say that the legislature cannot create, for instance, a municipal authority and give it power to make by-laws, or create a public authority with power to make regulations that shall have the force of law, or confer upon the Governor in Council power to make regulations having the force of law, or upon the Judges of the Court power to make Rules of Court having the force of law."
Baxter v Ah Way (1909) 8 CLR 626 per Griffith CJ at 632.

[58] See Dixon O, 'The Common Law As An Ultimate Constitutional Foundation', (1957) *Australian law Journal* **31**:240.

shortcomings of each area of law, I hope to also discover the possible disadvantages of public law regulation. This will provide a narrower framework within which to examine the applicability of the GTA to its subject matter and how, if at all, it could be improved.

Public vs Private Law. Perhaps the most rigidly maintained legal dichotomy is between the spheres of public and private law, for, as Chief Justice Dixon stated, the subject matters of private and public law are necessarily different'.[59] The division marks those laws and subject matters which affect the whole of society versus those that only affect individuals or small groups within society.[60]

As the supreme law maker the Parliament does retain the right to enter into the private law field, either by *jus particulare*[61] legislation or by enacting statutory rules, limiting or defining the scope of common law principles with respect to civil disputes.[62] On the whole, however, Parliament has, by choice, refrained from entering too dramatically into the private law field.[63] This is partially because of

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[59] *South Australia v The Commonwealth* (1962) 108 CLR 130, per Dixon CJ, at 140.

[60] "There is a clear distinction, and authorities binding on me treat it as an important distinction for these purposes, between decisions affecting the rights or interests of particular individuals and those affecting the interests, indiscriminately, of the members of the public at large or of the members of a section of the public." *Botany Bay City Council v Minister for Transport & Regional Development* (1996) 137 ALR 281, per Lehane J at par 31.

[61] A rule only affecting a special section of the nation or an individual. For instance, legislation dissolving a marriage, or a political party. There has been a steady decline of the *jus particulare* law, so that, apart from isolated cases, the Crown has opted for general statute to resolve interpersonal issues. For a discussion on the use of this form of legislation see Redlich J, *The Procedure of the House of Commons: A Study of its History and Present Form*, AMS Press Inc., New York, 1908/1969(reprint),. pp 256-257.

[62] For instance the recent IPP report, which seeks to establish legislative ceilings for negligence claims in Australia. See Ipp A, *Review of the Law of Negligence*, Report to the Minister for Revenue & Assistant Treasurer, Commonwealth of Australia, Canberra, 2002.

[63] English constitutional law is still deeply influenced by the conflicts of the 17th century and by the dominant constitutional theory of the 19th century. The former established the leading role of Parliament; the latter encouraged reliance on the ordinary courts' protection of the private, common law, rights of individuals to ensure the subjection of public power to the 'rule of law'. The courts and Parliament thus share the task of holding accountable those who exercise public power. The allocation of responsibility between them has depended on the legal nature, and the subject matter, of the powers concerned. Harden I, 'The Approach Of English Law To State Aids To Enterprise', (1990) *European Competition Law Review*, 3:**11**:101.

the historical dominion of the common law courts over private matters.[64] A more relevant basis for the modern day separation is that Parliament, as an agent of the 'whole people' [see above] must oversee the fate of the entire nation, rather than specific individuals within it.

What is perhaps most important to point out here is that whilst Parliament retains the ultimate power to enter the private field, individuals do not have reciprocal rights to enter the field of public law. This has been a basic and lasting restriction, so that, as the High Court notes:

> [b]y the end of the nineteenth century, it was generally accepted that an ordinary member of the public had no general right to invoke the aid of the civil courts to enforce public law rights or duties. Subject to exceptions, that remains the basic position in Australia today.[65]

In order to maintain the dichotomy of public and private the Courts have developed the doctrine of 'standing'[66], under which a party to a civil action must evidence a 'special interest' or 'special damage' beyond that which 'the public suffers as a whole'.[67] To invoke the jurisdiction of the courts the Plaintiff must prove the damaged suffered is beyond 'any side effect of the infringement of the public right'.[68]

Private law is then an insufficient mechanism for the resolution of the risk dilemma. It could only be invoked in a responsive manner where damage had accrued. It does not empower the whole of society, nor does it facilitate the

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[64] *Dr. Bonham's Case* (1610) 8 Co. Rep. 107a, 114a C.P.

[65] *Bateman's Bay Local Aboriginal Land Council v The Aboriginal Community Benefit Fund Pty Limited* (1998) HCA 49, per Gaudron, Gummow and Kirby JJ, at para 79.

[66] "It is quite clear that an ordinary member of the public, who has no interest other than that which any member of the public has in upholding the law, has no standing to sue to prevent the violation of a public right or to enforce the performance of a public duty" *Australian Conservation Foundation v The Commonwealth* (1980) 146 CLR 493, per Gibbs J at 526.

[67] *Bateman's Bay Local Aboriginal Land Council v The Aboriginal Community Benefit Fund Pty Limited* (1998) HCA 49; *Attorney-General for NSW v Brewery Employés Union of NSW* (1908) 6 CLR 469 at 550-552; *Tasmania v Victoria* (1935) 52 CLR 157 at 186-187; *London County Council v Attorney-General*,(1902) AC 165 per Lord Halsbury LC, at 168.

[68] *Helicopter Utilities v Australian National Airlines Commission* (1963) 80 WN(NSW) 48 at 54.

direction of the fate of society. One individual could not bring an action under the private law regarding the control exercised by gene technology over her or his, life, the lack of choice that it creates or the subjection to risks that it causes, because these are outcomes suffered by the public as a whole. The fact that private individuals are incapable of influencing the course of public affairs is all the more reason for the Parliament to intervene and enact public law principles for the control of the technology.

Hence, the risk society necessitates that gene technology be dealt with by public law.

THE CHOICE OF PUBLIC LAW

Whereas the private law sphere is dominated by case law the public law is the realm of legislation. Legislation can be broken up into two overarching categories, prohibition or regulation. Regulation can be divided into a variety of approaches. However, with respect to the following discussion, only statutory code and delegated legislation are relevant forms of regulation, as they are derive specifically from the legislative process. Each form of legislation has its own purpose, benefits and disadvantages both politically and legally.

Prohibition versus Regulation. Public statutes can be divided into two overarching categories, those which prohibit and those which regulate. Basically, prohibition and regulation mark differing degrees of acceptability and permissibility. Prohibition is obviously intended to ‘prohibit’ conduct, that is ban it altogether. Thus, it is about ‘absolute control’ of an activity, with no room for consent, discretion or permissibility.[69] At the other end of the spectrum is a completely ‘hands off’ approach in which the Government does not intervene at all. I have maintained that this is an unacceptable position for the Parliament to take and thus will not discuss it here. Regulation lies in-between these extremes.

Regulation is defined as '[a]ny laws or government 'rules' which influence the way people behave' irrespective of the form of such laws or who ultimately promulgates or enforces them.[70] To regulate something, is to place conditions on an activity to permit it *sub modo.* It necessarily imputes the exercise of discretion.[71] It is to 'direct' or 'control' a subject of public concern.[72] Regulation allows an overall policy to be discretionarily applied to 'individual situations' to determine whether they should be permitted or not.[73]

Both regulation and prohibition provide ultimate control over any activity or subject matter in the Crown. They are then both relevant to the risk dilemma, and could each have their unique place in ensuring the intervention demanded of the Crown. Thus, I will examine the benefits and disadvantages of both.

Prohibition is attractive, because it is a direct statement by Parliament that it is controlling risk, albeit by excluding it altogether, on behalf of the public. It is a clear, unequivocal statement of the Crown's control, supremacy and will to protect the community. Moreover, it is the 'safest' option, at least from the perspective of prohibiting hazards. On the other hand, by prohibiting the source of risks, we inevitably eliminate the source of benefits which may accrue from an activity. The Crown's obligation as an agent of the people is to act in their best interest, so the decision to ban something outright must also consider what detriment may be caused by the loss of that resource to the greater community.

Regulation, as opposed to prohibition, allows for a middle ground between the risks and benefits to be achieved. It evinces parliamentary recognition that both positive and negative aspects of an activity must be considered in reference to the community. Regulation is basically a balancing act between the interests of

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[69] *Country Roads Board v Neale Ads* Pty. Ltd. (1930) 43 CLR 126, per Isaacs, Gavan, Duffy JJ. at 138-139, *Swan Hill Corporation v Bradbury* (1937) 56 CLR 746, per Evatt J. at 771; *Ex parte Cottman; Re McKinnon* (1934) 35 SR7, per Jordan C.J. at 11.

[70] Office of Regulation Review, *A Guide to Regulation,* 2nd Ed, Commonwealth of Australia, Canberra, 1998.

[71] *Folely v Padley* (1984) 154 CLR 349 per Gibbs CJ at 354-359; *Melbourne Corporation v Barry* (1922) 31 CLR 174, per Higgins J at 208-209; *Swan Hill Corporation v Bradbury* (1937) 56 CLR 746, per Evatt J at 764, 771.

[72] *Radio Corporation Pty. Ltd. v The Commonwealth* (1938) 59 CLR 170 per Dixon and Evatt JJ. at 192.

[73] *ibid,* per Latham C.J, Rich, Starke and McTiernan JJ. At 183.

economic activity, social and technological advancement and the protection of the public health, safety and sensibility. Comparatively speaking, regulation does increase the chance of hazards occurring, because unlike prohibition it connotes some degree of exposure to risks by society. On the other hand it does leave room to ban certain aspects of an activity or undertaking and so could possibly overlap on a prohibition should the ambit of the empowering statute be wide enough.

With respect to the technological risk in general, regulation would seem the preferred option. The blame society does not advocate opting out of the 'risk game' altogether because it vehemently believes in the power of the technology to do both good and bad [see above]. Regulation allows the Parliament to take control of the technology on behalf of the people, in an attempt to maximise its benefits and minimise its burdens. To warrant the prohibition approach it would have to be shown that the technology in question was so 'risky', or so opposed by society, that it is simply unacceptable. As Stone notes, the public tends to demand prohibition of conduct that is universally opposed, but expects issues of moral ambiguity to be regulated.[74]

The Cloning Example. An example of the where the dichotomy between regulation and prohibition are necessary can be found in the related area of human cloning. Human cloning has two major outcomes. The first is for reproductive purposes, allowing a substantially genetically identical individual to be reproduced from a single human being.[75] The other is referred to as 'therapeutic cloning' and allows histocompatible cells and tissue lineages to be reproduced from a single human being. [76] It is hoped that this technology will one day allow the creation of cells, tissue and organs for the remediation of injury and congenital disease. [77]

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[74] Stone D, *Where the Law Ends. The Social Control of Corporate Behaviour*, Harper and Row, New York 1975, p 97.

[75] Wilmut et al. 'Viable Offspring Derived from Fetal and Adult Mammalian Cells' (1997) *Nature* **385**:810.

[76] See generally, *Nature* (2001) **414***:* 87-138.

[77] Trounson A, 'The Derivation And Potential Use Of Human Embryonic Stem Cells', (2001) *Reproduction & Fertility Development*; **13**:523-32

Like gene technology and indeed all the other technologies which fall under the umbrella of the blame society, cloning has caused mixed reactions, not least because 'the idea that humans can exercise such precise control over their reproductive processes' has caused a mixture of awe, fear, controversy and debate.[78] As such there has been a struggle to regain control over that technology by legislative intervention. These attempts all but languished, in Australia[79], and abroad[80] because they attempted to either, prohibit all human cloning or regulate all human cloning. This failed because legislators did not recognise the vast gulf in social attitudes towards each of the separate technologies.

Human reproductive cloning has drawn near unanimous condemnation worldwide, as being inherently unsafe, unethical and socially unacceptable.[81] Conversely, 'therapeutic cloning' remains contentious and the debate over the use of the embryo for therapeutic uses rages on.[82] Increasing media and social attention on the issue of cloning as well as the 'imminent' threat of a human clone being conceived forced the legislative agenda, which as noted above, constantly came up against the conflicting social demands to ban one technology and debate the other. Only when it was realised that the two technologies (reproductive and therapeutic) were fundamentally different in nature and purpose was a resolution found. The enactment of separate laws, in the Australia[83] and the UK,[84] prohibiting human cloning absolutely, and regulating the use of therapeutic

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[78] Gogarty B, 'Cloning Around With Words', in, Collected Works, *Regulating the New Frontiers: Legal Issues in Biotechnology*, Occasional Paper No. 4, Centre for Law & Genetics, Hobart, 2001. p 134.

[79] Nicol D, Gogarty B, Chalmers D, 'Human cloning and stem cell research', (2001) *Australian Health Law Bulletin* 3:**10**: 25-34. Gogarty B, 'Cloning Around With Words', in, Collected Works, *Regulating the New Frontiers: Legal Issues in Biotechnology*, Occasional Paper No. 4, Centre for Law & Genetics, Hobart, 2001. pp 136-141.

[80] Robertson J. 'Human Cloning and the Challenge of Regulation' (1998) *New England Journal of Medicine* **119**:339.

[81] Gogarty B, 'Cloning Around With Words', in, Collected Works, *Regulating the New Frontiers: Legal Issues in Biotechnology*, Occasional Paper No. 4, Centre for Law & Genetics, Hobart, 2001. pp 138.

[82] see generally Andrews K, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, House of Representatives Standing Committee on Legal and Constitutional Affairs Report, Commonwealth of Australia, Canberra, 2001.

[83] *Prohibition of Human Cloning Act (*Cth) 2002 and *Research Involving Human Embryos Act* (Cth) 2002.

[84] *Human Reproductive Cloning Act* (UK) 2001 and *Human Fertilisation and Embryology Act* (UK) 1990.

cloning succeeded where all previous attempts had failed.[85] In the US however, where bills continue to conflate the two issues, no legislative outcome has been reached, despite ever increasing demands for one.[86]

Gene Technology. The cloning example is evidence that in order to understand and reflect the public will, the Parliament must choose the form of its legislative intervention in a way reflective of the public sentiment towards that technology. Unlike cloning there is no major divide in how the public perceives gene technology. Rather, official surveys indicate the public has a tendency to see gene technology as one overall industry. [87] Moreover there is no unanimous opinion against gene technology. However, like cloning, the legislature finds itself operating between two broad constituencies with competing views about the proper realm of legislative interference that is necessitated by gene technology.

The public perspectives of gene technology are dealt with comprehensively in chapter 5. It is noted there that there are a broad spectrum of views. Such a broad spectrum is probably cause enough to use regulation over prohibition. However, for the sake of this discussion I wish to generalise somewhat and consider these perspectives in their ideological extremes. I do this because there are some who have argued vehemently for a moratorium or prohibition on GMOs [see 17.3]. Hence I wish to consider whether that approach was a tenable option for Parliament in considering the will of the people. I have therefore chosen to simplify the arguments into binary constituencies, as the choice of whether to regulate or prohibit is inherently binary. These constituencies are broader and more diffuse than mere pressure groups, though such groups may comprise their

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[85] Skene L, Gogarty B, 'A Legal Perspective on Stem Cell Research and Cloning' (2002) *Australasian Science* 8:**23**:31

[86] see Gogarty B, Nicol D, 'The UK's Cloning Laws : A View From the Antipodes' (2002) *Murdoch University Electronic Journal of Law* 2:**9**:8.

[87]The primary pre GTA study was undertaken by market research firm *Yann, Cambell, Hoare & Wheeler,* That study showed that of those surveyed, 'biotechnology' was most often associated with 'genetic engineering' which in turn was most often associated to 'modified food-general'. The survey indicated the public has a tendency to see 'Biotechnology' (gene technology in particular) as one industry. *Public Attitudes Towards Biotechnology Nationwide For Biotechnology Australia.* Yann Campbell Hoare Wheeler, Biotechnology Australia. 1999 :
<http://www.biotechnology.gov.au/library/content_library/BA_pYCHW.pdf> (7/12/02)

most visible and vocal components. They are, rather, conglomerations of ideologies, opinions and interests in agency activity.

Opponents of Gene Technology. I use the term 'opponents of gene technology', cautiously. These groups represent a large percentage of the visible debate on gene technology [see 3.5]. However, their position is not based on a complete denial of the benefits which may be derived from the technology. Rather, they are concerned that the technology is being improperly managed, introduced too quickly, without a proper understanding of the risks that it poses. They urge a fuller, more activist policy of enforcement, and advocate wider restraint on the use of GMOs in the interests of minimising harms which may arise from the technology, regardless of the extra costs to consumers, research or commercial enterprise. They distrust regulatory intervention because it is likely to be minimalist and ineffective, with the 'capture' effect tipped in favour of industry [see 9.4]. They have argued that a moratorium should be placed on the use of GMOs until they are proved safe, either in the whole of Australia or within regions of Australia to ensure that the choice to remain free of the technology is permitted [see 17.3].

Proponents of Gene Technology. Again this phrase must be approached with some caution. This group tends to see legislative interference as an unjustifiable intrusion by the State. Proponents of the technology do not deny outright that the it may pose risks. Instead they argues that the risks are no different than conventional methods or products. They consider legislative intervention to generally be burdensome and based on trivial or nonsensical issues such as the separation of GMO foods out from like products [see 13.2.2]. At the same time they play down the dangers of environmental harm arguing that little or no proof exists of dangers from GMOs beyond that of traditional agriculture. For the most part, proponents of gene technology argued during the inception of gene technology that there should be a completely 'hands off' approach by Government to the technology [see 3.2]. However, consumer backlashes towards the technology caused proponents to moderate their stance, arguing that government must be seen to be intervening, but only in a moderate, conservative sense which

would minimise the impediments of constant intervention and 'inordinate amounts of money' being spent on complying with bloated regulatory systems.

The Choice of Legislation. What can be seen from contrasting viewpoints is that neither advocates the most extreme option – complete freedom to operate, on the one hand, complete prohibition on the other. A 'moratorium' is not prohibition, it is a 'suspension of an activity' or time limited cessation of an undertaking.[88] It necessarily implies that the technology may eventually reap some benefits, and should be considered eventually. What the opponents of gene technology are therefore arguing is not an absolute refrain from the technology but the application of caution in considering the risks. Even the other side of the debate, does not promote (what I have argued to be) the untenable position of no governmental intervention whatsoever. Rather they argue for minimal intervention, or in other words no more than the usual caution applied to ordinary products.

Hence, gene technology is much more akin to 'therapeutic cloning' than it is to reproductive cloning. There is no social unanimity, but more importantly there are no moral, ethical or political absolutes. As part of the overall 'risk dilemma' gene technology naturally leads to regulation rather than prohibition.

[88] The CCH Macquarie Dictionary of Law, 2nd Ed 1996. P 112.

APPENDIX 5 : THE DELEGATED FORM

This Appendix complements the discussion in the text relating to the modern form of risk regulation. It explains both how and why delegated legislation is necessary to regulate gene technology.

CODIFICATION VS DELEGATION

The Office of Regulation Review describes several forms of regulation, including 'primary or delegated legislation … codes of conduct, advisory instruments or notes etc'. For the purposes of this discussion I wish to divide these forms of regulation into only direct and indirect intervention by Parliament. These are through express statutory codes, in which the standard, degree and limits of behaviour are spelled out within the statute itself, or through delegated legislation in which the spirit of the statute is administered to the subject matter.

Code Law. Code law is legislation which deals exhaustively with a subject matter in the body of the statute. The criminal law is the most explicit and readily cited example. However, defamation law, and some parts of employment, contract and corporations law have been subject to codification by Parliament.[1] Code law is much more akin to the traditional notion of 'legislation', in that it is created by Parliament and Parliament alone, with the intention to deal exhaustively with a subject matter.[2] It is meant to create final, decisive and unalterable standards of practice.[3] That is, it is the explicit statement of 'thou shalt' and 'thou shall not' within the body of legislation itself. In which Parliament specifically states what is to be acceptable and unacceptable conduct by members of society.

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[1]Smith G.F, *Public Employment Law*, Butterworths, Sydney, 1987, pp 94-96; *Minors (Property and Contracts) Act* 1970 (NSW) ; *Defamation Act* 1889 (Qld) ; *Statute Law Revision Act* (No 2) 1995 (Qld) ; *Defamation Act* 1957 (Tas) ; *Corporations Act* 1989 (Cth).

[2] Times have changed, and the judges are unwilling to pretend belief in the Diceyan theory that Parliament effectively supervises all derogations from the presumption of liberty and that "every act which affects the legal rights, duties or liberties of any person must be shown to have a strictly legal pedigree". Dicey "The Law of the Constitution" Chap. 4, summarised in Wade W, Forsyth C, *Administrative Law*, 7th ed, Oxford University Press, Oxford, p. 24.

[3] *Thomas v The King* (1937) 59 CLR 279 per Dixon J at 304; *Brennan v The King* (1936) 55 CLR 253, Dixon and Evatt JJ at 263; *R v Sabri Isa* [1952] St R Qd 269 (CCA), Stanley J at 293.

Because Code Law is enacted directly by the Parliament, it has a natural proximity to the will of the people. This is because it is elected officials who are directly responsible for its content and form. Moreover because it is set out it primary legislation it will, as Bentham states, ‘mark out the line of the subject's conduct by visible directions instead of turning [the subject] loose into the wilds of perpetual conjecture’.[4]

Whilst the concept of an entirely closed and controlled regulatory process may have seemed to jurisprudentially attractive, the need to constantly refine legislation to counter various contingencies created by some subject matters proved logistically impossible for Parliament to achieve.[5] Just as the people could not easily repeat the exercise of their collective will [see above], there were certain subject matters Parliament could not repeatedly exercise its legislative powers. As Dicey maintained, there were some subjects for which the ‘cumbersomeness and proxility’ of the legislative process could not deal, because the Parliament was simply ill resourced, and ill fitted to ‘work out the details of large legislative changes’.[6]

DELEGATED LEGISLATION.

The shattering of the ideal that Parliament could legislate completely on everything came, pertinently, with the rise of the industrial revolution, and modern medicine.[7] That is with the very seeds of the risk society. During the mid nineteenth century, the spread of diseases such as cholera were a major threat to public health and safety. An increasing knowledge of medicine and the associated

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[4]Attributed to Jeremy Bentham cited in *Byrnes v The Queen* (1999) HCA 38, per Gaudron, Mchugh, Gummow And Callinan JJ. at para 11.

[5] *ibid.*

[6] Dicey A.V, *Introduction to the Study of the Law of the Constitution.* 10th ed. Macmillan, London, 1915/1959 (reprint), p 69.

[7] Note, that the 19th C form of delegated legislation was not entirely new, the delegation of powers has been traced back to the mid 16th C. However, these was a rather infrequent occurrence and subsequent to the ‘glorious revolution’ and the doctrinal supremacy of Parliament delegated legislation was extinguished. However it was in the 19th C that the increase in industrialisation and the increasing role of government

recognition of the importance of public sanitation led to the realisation that certain contingencies could be put in place to avoid, limit or destroy certain diseases. However, Parliament could not make specific provisions for each and every locale where the disease existed or threatened. Hence in 1832 the British Parliament enacted legislation which permitted:

> with a view to prevent … the spreading of [cholera] … cities, towns or districts affected with or which may be threatened with the said disease … to establish such rules and regulations by the authority of Parliament.[8]

This marked the beginning of the delegation of Parliamentary powers to subordinates, which posited Dicey would provide flexibility to the law, by allowing 'the executive [to] work out the detailed application of general principles embodied in Acts of Parliament'.[9]

By the time of Federation in Australia, the 'British Statute Book abound[ed] with examples of' delegated legislation so that 'it cannot be supposed' that the Australian Parliament was not intended to have similar 'conditional legislation as within the scope of the legislative powers which it from time to time conferred'.[10] The right of the Crown to validly delegate its powers was confirmed by the High Court in a series of cases,[11] and definitively settled in *Victoria Stevedoring v Dignan*[12] in which Evatt J. stated:

> The true nature and quality of the legislative power of the Commonwealth Parliament involves, as part of its content, power to

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forced a revival in this form of regulation. [see Craig P, *Administrative Law*, 2nd Ed, Street & Maxwell, London, 1989 pp 173-174].

[8] cited in Miers D, Page A, *Legislation*, 2nd Ed, Street & Maxwell, London, 1990, p 107.

[9] Dicey A.V, *Introduction to the Study of the Law of the Constitution.* 10th ed. Macmillan, London, 1915/1959 (reprint).

[10] *Baxter v Ah Way* (1919) 8 CLR 626 per Griffith CJ .at 634.

[11] *Farey v Burvett* (1916) 21 CLR 433, *Baxter v Ah Way* (1919) 8 CLR 626, *Roche v Kronheimer* (1921) 29 CLR 329

[12] (1931) 46 CLR

> confer law-making powers upon authorities other than Parliament itself[13]

Delegated legislation has come to dominate the legislative process and the volume of delegated legislation increases every year.[14] It is the predominant manner in which various aspects of every-day life are regulated.[15] Pearce forwards three primary reasons why delegated legislation has been preferred to statutory code by Government.

- It allows for a level of technical detail to be considered which is simply beyond the comprehension, resources and time of a Parliament constituted of lay members;
- It allows legislation to be dynamic and the deal with rapidly changing circumstances,
- It allows for emergencies.[16]

Delegated legislation is the obvious choice for the solution of the risk dilemma because it solves the first major element of that dilemma, namely that 'technology makes risk more of a guessing game than ever' Because science and technology constantly restructures and reinvents itself, code law would quickly become redundant, requiring constant 'quick fixes' or updates by Parliament. Novel science such as gene technology presents an 'uncertain future', which can never be fully determined. If we chose to regulate rather than prohibit technology outright that regulation will be formed in technical, economic and logistic 'fog', in that we can never completely determine its scope or impact.[17]

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[13] *ibid.* at 119.

[14]Administrative Rule Council, *Rule Making by Commonwealth Agencies*, Report (No 35M) Attorney Generals Department, Commonwealth of Australia, Canberra, 1992.

[15] Douglas R, Jones M, *Administrative Law*, 3rd ed., Federation Press, Sydney, 1999, pp 271-272.

[16] Pearce D, *Delegated Legislation in Australia and New Zealand*, Butterworths, Sydney, 1977, p 2.

[17] Daintith T, *Legal Measures And Their Analysis: Law As An Instrument Of Economic Policy: Comparative And Critical Approaches*; Walter de Gruyter, Berlin, 1988, 30.

With respect to gene technology the ‘fog’ is particularly thick, the outcomes and risks cannot be said to have been completely evaluated not only because of insufficient time to test novel products but simply because many of these products and practices are yet to be invented. The form of regulation to oversee this technology must then necessarily permit a long term evaluation of the risks of a technology, not a short term evaluation which attempts to ascertain inherently unforeseeable outcomes.

The static nature of statutory code makes it an unsuitable device with which to establish standards of dealing with GMOs because of the time and cost which is required to alter it. In arenas such as the criminal law which are relatively stable predictable areas of human interaction, it is possible and indeed attractive to place standards of practice directly within the primary legislation itself. In those areas of law changes in social standards with respect to the behaviour or activities in question are infrequent. Society has reached a relatively stable conclusion on what forms of harm are permissible or not. Genetic technologies, however, will continue to force a reassessment of what is acceptable and unacceptable. Our notions of, and perception of, risk will evolve and change with the technology. The regulation of a subject matter in such flux then demands delegated legislation.

REGULATION, DELEGATION AND SOVEREIGNTY.

Recognising that a delegated, regulatory scheme is the most effective solution to the risk dilemma does not that it is perfectly suited to it. The very aspect of delegated legislation which makes it so suited to solving that dilemma can also be seen to undermine the solution provided by legislating in the first place. By ‘delegating’ Parliamentary law making the Crown is effectively creating agents of its own to undertake the law making process which, was arguably given solely to it.

The effect of offsetting part of the law making process to outside agents is to create a greater distance between the people and the body exercising their sovereign will. Moreover, by delegating the law process to a body outside Parliament, the people lose (at least appear to lose) the stringent protections they

placed on the exercise of sovereign power [see above]. Craig, suggests that there is a fourth political motivation behind delegated legislation (additional to the three set out by Pearce [directly above]), being that it allows the political legislature to create broad skeletal legislation, leaving the often controversial detail to be dealt with by the executive.[18] In doing so the Parliament avoids the political repercussions of unpopular behaviour (i.e. that which are contrary to the public will). As such, delegation can raise the ire and consternation of many in the community, because it appears to 'bypass the democratic process', or as one Senator argued '[I]f you believe that Parliament is an expression of the will of the people, then [it] goes right against the will of the people'.[19]

Thus, where the second element of the risk dilemma, being, 'who should decide', appeared solved by invoking the Crown as the ultimate law maker, the determination of 'how they should decide' actually rendered that first element uncertain again.

The Justification for Delegation. The Constitution makes no express provision for the delegation of legislation, but, as noted above, the High Court has found that the subordination of the law making power is within the legislative capacity of the Crown. Dixon J admitted that by allowing the intermeshing of the executive and legislative branches in such a way may appear 'an inconsistency, or at least, an asymmetry',[20] when contrasted with the rigid dichotomy the Courts maintained between the judicial and legislative branches (which justified the basis for judicial review of legislative behaviour). However, he argued that the history and usage of the common law dictated that delegation was a necessary component of legislative power. For him the question was not whether delegation *prima facie* diminished the Crown's power, but whether the extent of any given case of delegation had been 'taken too far'.[21]

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[18] Craig P, *Administrative Law*, 2nd Ed, Street & Maxwell, London, 1989, p 175.

[19] cited in Douglas R, Jones M, *Administrative Law*, 3rd ed., Federation Press, Sydney, 1999, p 282.

[20] *Roche v Kronheimer* (1921) 29 CLR 329.

[21] *ibid.* at 335. see also *Crowe v The Commonwealth* (1935) 54 CLR 69. The Privy Council affirmed the position of Dixon, and the rest of the High Court in the *Boilermakers Case*, stating:"The delegation of regulative power by the legislature to an executive body does not mean that the legislature has abdicated a

Thus, delegated legislation is acceptable and indeed a necessary aspect of governance, so long as Parliament retains ultimate control. It is at this point that the courts have advocated caution, and sought to build, in partnership with the Parliament, rules ensuring that Parliament remains the sole body responsible for the exercise of power, and that such power is within the limits prescribed by the Constitutional framework under which the Crown operates.[22]

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power constitutionally vested in it. For the executive body is at all times subject to the control of the legislature". (1957) 95 CLR 529 at 527.

[22] Wharam A, 'Judicial Control of Delegated Legislation' (1973) *Modern Law Review* **36:** 611–12

APPENDIX 6 :

THE PRECAUTIONARY PRINCIPLE

This Appendix examines various arguments during Gene Technology Debates relating to the inclusion of the Precautionary Principle in the Gene Technology Act.

DEBATE OVER THE PRECAUTIONARY PRINCIPLE

As noted in the main body the *Gene Technology Act* 2000 (Cth) (GTA/the Act), was according to the Interim Office of the Gene Technology Regulator (Interim OGTR), a 'generally cautious approach'.[1] The Interim OGTR submitted that a cautious approach to all levels of the decision making process was much clearer than utilising a generalist over-reaching concept which would be subject to misinterpretation.[2] It is an interesting aside to consider that the regulatory office that would eventually be subject to this principle was against its incorporation in the Act from the outset. However in the principle took central stage in parliamentary debates over the Bill. The debate is interesting in the current discussion because it provides a good insight into the differing perspectives on risk and risk analysis (the science/policy dichotomy) and the differing policy approaches of the enacting parliament.

Government Opposition to the Principle. Early Parliamentary discussion of the precautionary principle began in the lower house with a clear divide between the Government and Opposition. The Opposition voiced concerns about the lack of a precautionary principle within the Act.[3] However the Government, at least at first, vehemently opposed to the inclusion of the principle. They declared that

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[1] Submission No.77, p.74 (IOGTR), to the Senate Committee : <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[2] *ibid;* Additional Information dated 18 September 2000. See also *Committee Hansard,* 25.8.00, p.381 (Avcare Ltd).

[3] See generally *House Hansard* pp 19473-19536.

introducing the precautionary principle would encourage 'unfounded and irrational decision making processes'.[4]

The Government claimed that the principle demanded 'anticipatory action' unless there was evidence beyond reasonable doubt that harm would not occur.[5] This they posited presented the 'potential to do enormous damage to Australian trading interests'[6] Accordingly, the principle needed to be 'kept well away from this important technology'.[7] Rather, argued the Government 'balanced risk assessment is what this ought to be all about.'[8]

Industry Opposition to the Principle. The position of industry on the use of the precautionary principle was put by Avcare's (an industry group of agricultural manufacturers and distributors) submission to the Senate Committee. Avcare submitted that 'the precautionary approach can be applied to managing that risk once the risk has been properly assessed.'[9] This seems a much more tempered approach than that adopted by Government. So was the Government wrong in attempting to protect industry from its influence? The answer is probably not at all, but simply that Avcare's position was couched in more political language than the Government's. By the time of the Senate Committee (the Senate Committee [see 3.7]) it was becoming clear that the principle was taking centre stage.[10] The careful choice of words was explained later when it was clarified that Avcare did not:

> subscribe to the proposition that the precautionary principle should be used for risk assessments. What we are saying is that a precautionary approach should be applied to risk management. Once an organism has been approved, then it has to be managed

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[4]Washer M '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 28/8/2000, 19463.

[5]Thomson A, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 28/8/2000, p 19470

[6] *ibid.*

[7]*ibid.*

[8] *ibid.*

[9] Senate Committee Hansard 25/8/00 p 377

[10] A vast number of submissions contained reference to the principle and the Committee was taking an active interest in the principle. See Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000, paras 3.21-3.74.

> under farming conditions, and we have a lot of examples where best management practice is the tool to actually manage that risk.

Here there is a clear demarcation, not only between risk assessment and risk management but between precautionary *principle* and precautionary *approach*. The phrase 'principle' connotes a strong foundation which is the cornerstone or over reaching standard that must be observed. An 'approach' however is generalist and less necessary to observe in all circumstances.

What is equally interesting to glean from the above quote is the definition of risk management promoted by Avcare. According to Avcare risk management occurred under 'farming conditions' *not* 'trial conditions' (as all GMO crops were at that time). Risk management, according to this definition, occurred on the field, after a the product had been commercialised. This would seem to imply that standards applied during the trial phase should not have to be formulated in accordance with the precautionary principle. Under the GTA, trial conditions will be licensed and farm conditions will fall under the less stringent registered dealing bracket [see 4.5]. Hence it would seem that Avcare was suggesting that only the commercial, farm-scale release of crops should be subject to a precautionary approach. The implications being that to do so before this stage would inhibit the entry of products to market.

Understanding Policy Through Language. Both Avcare's and the Governments opposition to the concept of a principle relied vague interpretation of 'risk assessment' and 'risk management'. Within government debates these terms often overlapped so that the principle was often referred to as being undertaken during, or impacting upon, 'risk assessment'.[11] Given the Australian convention of describing the overall process of risk governance as 'risk assessment' [see 7.2] it was often hard to tell what was meant by this. Moreover, only once in the whole of the debate over the Gene Technology Bill – in either house of Parliament

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[11] Tambling G, '*Gene Technology Bill* 2000 … Second Reading', 8/11/2000, *Senate Hansard*, p 19369; Thomson A, '*Gene Technology Bill* 2000 … Second Reading', *House Hansard*, 28/8/2000, p 19470.

– did the Government refer to the principle as a risk management tool.[12] This was to argue that because it required 'anticipatory action' and thus would impact on risk assessment. So even if the principle was a risk management device it 'crept into' risk management..

What can be seen is a concerted effort to set the definition of risk assessment so broad as to incorporate part of the decision making process and thereby play off the precautionary principle against risk assessment. Several reasons for this may be considered.

The Uncertainty 'Trigger'. If the precautionary principle is tied into risk assessment it is much easier to attack. Associating the two creates the appearance that as soon as any uncertainty is discovered, the risk assessment ceases, and the complete picture of risk is never really discovered. The principle is cast as a 'trigger' that ceases risk assessment as soon as uncertainty arises. Thus, the principle has been condemned as 'block[ing] the development of any technology if there is the slightest theoretical possibility of harm'.[13] Yet to suggests that lack of full scientific certainty automatically *disallows* an activity is a misstatement of the principle. In fact the principal states the exact opposite, that lack of full scientific certainty should not *of itself* be relied upon to *allow* an activity.

Irrationality. The irrationality claim is also reliant on overlapping the precautionary principle and risk assessment. In inserting the principle into this aspect of regulatory governance it can be argued that the issues become confused and science will be caught up in a quagmire of 'misconceptions and fears'. In other words science and policy will overlap contrary to international best practice [see 7.3]. The Government's claim that the principle would lead to an 'erosion of science based decision making'[14] could only be true if it was part of the risk

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[12]"[The precautionary principle] basically says that, if there is a level of scientific uncertainty in a decision making process, anticipatory action should be taken to prevent any harm that may happen, as it has not been proven beyond any reasonable doubt that it will not. " Washer M, *Gene Technology Bill* 2000 …: Second Reading', *House Hansard*, 28/8/2000, p 19463.

[13]Holm S, Harris J, 'Precautionary Principle Stifles Discovery.' (1999) *Nature*, **400**:398

[14]Tambling G, '*Gene Technology Bill* 2000… Second Reading', *Senate Hansard*, 8/11/2000, p 19369. see also Washer *op cit 4*.

assessment process because this is the process of scientific evaluation. The Bill already contained provisions for the Regulator to consider ethical and community interests during risk management. The argument seems rather tenuous for this very reason, in that if the principle somehow impacts on risk assessment why do community and ethical considerations not also? Furthermore, it neglects to recognise the principle only considers scientific certainty or as the case may be scientific uncertainty and not any other manner of consideration.

By manipulating the language of risk opponents of the principle are able to indicate that the outcomes of its application would be fallible and biased. Establishing however that the principle is a decision making tool, that is about measures taken in response to risk identification rather than measures which must be undertaken during risk identification undermines the validity of such criticisms. Where applied to the standard setting process the principle cannot of itself create bias or import any greater uncertainty than would occur without it, because the Regulator already has a number of sources of information which will impact on the final outcome.

Source of Governmental Policy on the Principle. Evidently industry may experience some overall pecuniary loss from obliging the Regulator to consider the what information is lacking during the standard setting process. Their resistance then is understandable, but at least they recognised the need to maintain public image and support a general concept of precaution. What drove the Government to such a obdurate rejection of the principle? The need to cater to the industry constituency would have played a part, but from the number of submissions to the Senate Committee, supporting the principle there would seem to be political pressure in the opposite direction.

One answer to the Government's position on the principle are the several references to the 'international standing' or 'international reputation' of Australia. This is not to say the principle is contrary to international law. In fact the opposite is true, with it being enshrined in several international documents.[15] Nor

[15] *op cit* 12.

does it reflect the need for Australia to maintain regional dissent to counter the claim that the principle has or will form international custom for it has been adopted in several Australian domestic Acts.[16] Instead, it marks the shift towards a policy alignment with that of the United States (US), regarding gene technology and agriculture.[17]

Whilst the US ratified the *Rio Declaration* and hence is bound to the principle under international law it has never given the principle any express legislative form in its domestic legislation. Instead it claims that its laws have a generally precautionary *approach* [18] 'embedded in them'[19] rather than expressly stated. [20] Representatives of US government agencies are directed to avoid any reference to the 'precautionary principle' and instead use terms such as 'science based risk assessments'.[21] At the heart of the US concern is a very open sentiment that the precautionary principle would impact on trade in its products on the world market under the GATT[22] and WTO rules.

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[16] *ibid.*

[17] The alignment with US foreign policy arose primarily at the time of talks over the *Biosafety Protocol*, where Australia joined a group of like minded nations, headed up by the US, to oppose the implementation of the protocol. The group comprised of Argentina, Australia, Canada, Uruguay and the United States, and has been since entitled the 'Miami Group', that has continued to oppose strict rules governing GMO commerce at the international level. See Schulz E, 'GMOs and the global trading system; (2000) *Journal of Agricultural Lending*, 1:**14**:22; Masood E, 'Collapse Of Talks On Safety Of GMO Trade', (1999) *Nature* **398**: 6.

[18]Office of International Information Programs (US), *United States Position on Precaution*, US Dept of State, International Information Program Publication, Washington D.C, 2000.

[19] Codex Document CX/GP 00/3-Add.6, under Agenda Item 3.1, for the 15th Session of the Codex Committee on General Principles, Paris, 10-14 April 2000

[20]The US has continually emphasised the need for qualified risk assessment based solely on scientific evidence rather than extending the current system 'beyond that which is built into the risk assessment process'. See Larson A, "Making Good on Biotechnology's Global Potential " Address to World Food Prize Symposium Luncheon, Des Moines, Iowa (12/10/200), USDA Publication, Washington DC., 2000.

[21] President's Council on Food Safety(U.S. Department of Agriculture, Department of Health and Human Services, Environmental Protection Agency Department of Commerce) Strategic Planning Task Force Public Meeting January 19, 2000 Date: Wednesday, January 19, 2000 :
<http://www.foodsafety.gov/~fsg/ctr0001.html>

[22] *General Agreement on Tarrifs and Trade*, Oct. 30, 1947, 61 Stat. A-11, TIAS. 1700, 55 UNTS.

The US has consistently argued against express declarations of a 'principle' which has been suggested by the EU and others in any international agreement regarding gene technology because the:

> concept means that an industrial activity or [genetically modified] product … that is thought to cause harm would be banned even if little or no scientific evidence exists that it might be harmful.[23]

It argues that instead of being rational and science based it 'could become an arbitrary and political means of excluding imported products for any reason'.[24] This concern was brought to bear in the talks over the *Cartagena Protocol on Biosafety* (Biosafety Protocol [see 7.1.2]) – where the US, – who despite not having ratified the Convention on Biological Diversity[25] (to which the protocol is annexed) – became the dominant figure in the negotiation.[26] The US brought with it an unprecedented number of agrochemical and gene technology companies and associations, a rather uncommon feature at international intergovernmental negotiations.[27] It also headed the 'Miami Group' of 'like minded' countries, that represented the worlds largest agricultural exporters. The Miami group includes Australia.

One of the core concerns of these groups was the use of the precautionary principle in that agreement. The Miami Group placed strong pressure on all members to avoid use of the principle based on the argument that it would render

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[23] Department of State (US), *U.S. Codex Delegation Seeks Science-Based Food Safety Guidelines*, <http://usinfo.state.gov/topical/global/biotech/00040603.htm> (13/2/03)

[24] Department of State (US), *Biotechnology Initiative Expands Regulatory Process, Plan Strengthens Role Of Three Agencies*, <http://usinfo.state.gov/topical/global/biotech/00050302.htm> (13/2/03)

[25] Redick T, *et al*, 'Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path within the *Biosafety Protocol*', (1997) *Environmental Law* **4**:16.

[26] *op cit*, 17.

[27] Conference of the Parties to the Convention on Biological Diversity, *Draft Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity*, First Meeting Report, U.N. Doc. UNEP/CBD/ExCOP/1/L.2/Rev.1, Montreal, 1999, paras. 3, 4.

international trade rules uncertain and unattainable.[28] Instead of the precautionary principle or approach it was argued, there should be "scientifically sound" risk assessment.[29]

The similarity of the US rhetoric on the precautionary principle and that of the Australian Government's during Gene Technology Bill debates is striking. What must be realised is that the Parliamentary debate on the GTA occurred within months of the Montreal (Biosafety Protocol) negotiations. As part of the US led Miami group Australia played a large part in attempting to minimise the effect of that protocol and more importantly the importance of the precautionary principle within it. There is little doubt that the Montreal negotiations played a large part in the policy of the Australian Government during the GTA debates.[30]

Risk Language as Obfuscating. In reality the opposition to the precautionary principle derived not so much out of the want of 'good science' over 'bad policy', but 'good trade' and 'good development'. These are definitely laudable aims, and should necessarily be considered as part of the government's obligation to take control of technological development. Nevertheless the above discussion is evidence of the often hazy divide between science and policy and how the call for 'good science' can often obfuscate an underlying agenda as much as 'bad policy', 'bad science' or 'non scientific' claims can.

The Importance of the Principle in the Risk Dilemma. If regulation is to truly exercise power over technology, and effectively control its risks and its benefits, in a manner which benefits the people as a whole, the precautionary principle seems to be demanded. The risk dilemma, presented by novel technology requires, decision makers to play a 'guessing game', because there will *always* be a degree of uncertainty and a lack of knowledge, data and variables. Certainly there will never be a way of truly ascertaining what is unknown in such a

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[28] Gupta A, 'Advance Informed Agreement: A Shared Basis For Governing Trade In Genetically Modified Organisms?' (1999) *Indiana. Journal of Global Legal. Studies* **9**:265.

[29] *ibid.*

[30] *op cit* 17.

circumstances, but to not take the unknown into account at all would seem foolish.

It is important to know about the gaps which are being filled in during risk assessment. Otherwise there is a potential that we are proceeding blindly into an enterprise, merely because we know nothing about it. To turn the objectors argument on its head, would seem to indicate that we *must* permit *every* technology unless we can prove from the outset that it is risky. Yet if we have no data about risk we must continue until there is a disaster sufficient enough to provide risk data. Undertaking such an approach to risk management would seem contrary to the objective of controlling the technology in a way that best decides societies fate.

THE INCLUSION OF A PRINCIPLE.

The passage of the Gene Technology Bill through the House in the absence of a precautionary principle attracted criticism from various sectors. The Australian Centre for Environmental Law argued that the:

> precautionary principle finds its basis in the principles of economically sustainable development which should also be taken into account by the [Regulator] in deciding whether to issue a licence.[31]

Senator Brown (Greens) argued that the precautionary principle was an 'essential recognition of the significant risks inherent in gene technology' and must be included in the final Bill.[32] The Senate Committee agreed, stating an explicit recognition of the precautionary principle was necessary to provide 'clear direction' to the Regulator approaching risk management required caution.[33] The

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[31] Submission No.34, p.5 (ACEL), to the Senate Committee <http://www.aph.gov.au/senate/committee/clac_ctte/gene/ca_gene.htm> (12/12/02).

[32]Brown B, *Senate Inquiry Report Into Genetic Engineering Does Not Go Far Enough*, Press Release (1/11/2000), The Greens, 2000.

[33] Senate Community Affairs References Committee, *A Cautionary Tale: Fish Don't Lay Tomatoes*, Commonwealth of Australia (AGPS), Canberra, 2000, para 4.70.

Committee recommended adopting the interpretation of the principle set down in domestic legislation under the *Environment Protection and Biodiversity Conservation Act* 1999 (Cth) (the Environment Act). That Act states:

> [t]he precautionary principle is that a lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage.[34]

Labour took up the Senate Committee's recommendations and tabled an amendment to the Gene Technology Bill in the Senate.[35] However, it extended the Environment Act definition to include not only environmental damage but the prevention of harm to human health. It also scrapped the phrase 'damage' and replaced it with degradation.[36] This, they argued, would provide the Regulator direction on how to apply precaution to standard setting.[37]

The Government maintained its position that the precautionary approach would, create confusion and uncertainty.[38] Research, the Government asserted, would take up 85% of the Regulator's activities and the precautionary principle would 'stymie' the potential for research and innovation (something akin to Avcare's submission above]). Pressure from the Opposition and all minor parties[39] softened the Government's stance. The Government moved from 'strongly' opposing the principle, to 'strongly' opposing the wording adopted by the Opposition. In particular, it criticised the inclusion of 'human health' within the principle's definition. To do so, argued the Government, would extend the principle beyond the definition of precautionary principle under Principle 15 *Rio Declaration,* and it had been Australia's position internationally to argue against

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[34] s. 391 *Environment Protection And Biodiversity Conservation Act* 1999 (Cth)

[35]Gibbs B, 'Gene Technology … Second Reading Date', *Senate Hansard,* 7/11/2000, p 19304.

[36]*ibid.*

[37] *ibid.*

[38]Tambling G, '*Gene Technology Bill* … Second Reading', *Senate Hansard*, 8/11/ 2000, p 19369.

[39] Sidebottom S, '*Gene Technology Bill* … Second Reading', *House Hansard* 29/8/2000, p 19536; Stott-Despoja N, '*Gene Technology Bill* 2000 … Second Reading', *Senate Hansard* , 7/11/2000, p 19291; Harris L, '*Gene Technology Bill* 2000 … In Committee', 7/12/2000, *Senate Hansard*, p 21205.

extending the *Rio Declaration* any further.[40] The Government also argued that in keeping with the *Rio Declaration* the words 'cost effective' should be used. [41]

The Opposition party subsequently dropped the reference to human health and included the words 'cost effective'.[42] The other minor parties (Greens, Democrats, One Nation) introduced amendments to include human health and discard the reference to 'cost effective' but the Labour amendment succeeded to their detriment (the final principle was set out above [see 4.5].

[40] *ibid.*

[41]Tambling G, '*Gene Technology Bill* 2000 … In Committee', *Senate Hansard*, 7/12/2000, p 21204.

[89] Forshaw M, '*Gene Technology Bill* 2000 …: In Committee', *Senate Hansard*, 7/12/2000, p 21208.